UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-35994

HEAT BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**26-2844103**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification Number)*
627 Davis Drive, Suite 400 **Morrisville, NC** *(Address of Principal Executive Offices)*	**27560** *(Zip Code)*

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

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

Title of Class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0002 par value per share Common Stock purchase rights	HTBX	NYSE American LLC

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

As of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $169,016,850 (based upon the closing sale price of the registrant's common stock reported on that date). This calculation excludes shares held by the registrant's current directors and executive officers and stockholders that the registrant has concluded are affiliates of the registrant.

As of March 9, 2022, the issuer had 25,649,824 shares of common stock outstanding.

Documents incorporated by reference: None.

HEAT BIOLOGICS, INC.

FORM 10-K

TABLE OF CONTENTS

PART I

Forward-Looking Statements

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

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

Summary Risk Factors

Our business faces significant risks and uncertainties of which investors should be aware before making a decision to invest in our common stock. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. The following is a summary of the more significant risks relating to the Company. A more detailed description of our risk factors is set forth below under the caption "Risk Factors" in Item 1A in Part I of this Annual Report.

Risks Relating to Our Company, Financial Position and Capital Requirements

- We have a limited operating history with which to compare and have incurred significant losses since our inception and expect to incur substantial and increasing losses for the foreseeable future.
- We have a limited operating history conducting commercial development of bioanalytics, process development and manufacturing activities, which may limit the ability of investors to make an informed investment decision.
- We will need to raise additional capital to support our long-term business plans.
- We do not anticipate generating revenue for many years.
- Business disruptions including coronavirus could adversely impact our business.
- We currently have no product revenues and may not generate revenue at any time in the near future, if at all.
- We are substantially dependent on the success of our product candidates.

Risks Relating to Our Clinical Development, Regulatory Approval and Commercialization

- If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented
- If we do not obtain the necessary regulatory approvals, we will not be able to sell our product candidates.
- Our product candidates are in the early stages of development and each will require extensive testing and funding.
- Clinical trials are very expensive, time-consuming, and difficult to design and implement.
- Misidentification of cell lines could impact our clinical development and intellectual property rights.

- There is uncertainty as to market acceptance of our technology and product candidates.
- We currently rely upon our gp96 platform for development of many of our product candidates.
- We may not be able to compete successfully for market share against other drug companies.
- We rely on our employees and third parties for our development program.
- For our ongoing clinical trial of HS-110, we are administering our product candidates, in combination with other immunotherapy agents and any problems obtaining the other immunotherapy agents could result in a delay or interruption in our clinical trials.
- 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.
- Adverse effects resulting from other immunotherapy drugs or therapies could also negatively affect the perceptions of our product candidates.
- We will continue to be subject to ongoing and extensive regulatory requirements.
- We have no experience selling, marketing or distributing products, and have no internal capability to do so.
- We may not be successful in establishing and maintaining strategic partnerships.
- 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 ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.
- Legislative and regulatory changes affecting the health care industry could adversely affect our business.
- We may incur substantial liabilities.
- The U.S. government may have “march-in rights” to certain of our intellectual property.
- Reliance on government funding for Pelican’s programs may impose requirements that limit Pelican’s ability to take certain actions, and subject it to potential financial penalties.
- We rely extensively on our information technology systems and are vulnerable to damage and interruption and any failure to maintain the security of information
- Any failure to maintain the security of information relating to our customers, employees and suppliers could expose us to litigation, government enforcement actions and costly response measures.
- We may face particular data protection, data security and privacy risks in connection with the European Union’s Global Data Protection Regulation and other privacy regulations.
- Our operating results may be adversely affected by fluctuations in foreign currency exchange rates.
- We could be adversely affected by violations of the U.S. and other worldwide anti-bribery laws.

Risk Related to the Pending Merger and Elusys

- If the conditions to the Merger are not met, the Merger will not occur.
- The combined company may not experience the anticipated strategic benefits of the Merger.
- Our Chief Executive Officer and Chairman of the Board of Directors has a conflict of interest that may influence him to support funding of Elusys.
- We may be unable to successfully integrate the Elusys businesses with our current management and structure.
- Elusys is substantially dependent on various US Government contracts that are material to its business.
- We do not anticipate generating revenue from Anthim sales, upon consummation of the pending acquisition of Elusys, for several years.
- Our ability to generate product revenues from Anthim is dependent upon government spending and compliance with the government contracts.
- To date, Anthim has been sold to a limited number of customers.
- In order to develop Anthim, upon consummation of the pending acquisition of Elusys, we will have to devote significant resources to Anthim.
- Elusys has been manufacturing the drug product with one manufacturer pursuant to the terms of an exclusive manufacturing agreement.

Intellectual Property Risk Factors

- We have limited protection for our intellectual property, which could impact our competitive position.
- The technology we license, our products or our development efforts may be found to infringe upon third-party intellectual property rights.
- We rely on a license to use various technologies that are material to our business.
- We may be unable to generate sufficient revenues to meet the minimum annual payments or developmental milestones required under our license agreements.

General Risk Factors

- Our stock price has fluctuated in the past, has recently been volatile.
- If our acquired intangible assets become impaired, we may be required to record a significant charge to earnings.
- We rely on key executive officers and scientific, regulatory, and medical advisors.
- Our failure to meet the continued listing requirements of The New York Stock Exchange could result in a de-listing of our common stock.
- Our shares of common stock are from time to time thinly traded.
- Our need for future financing may result in the issuance of additional securities that will cause dilution.

Item 1. *Business*

Overview

We are a fully integrated biopharmaceutical company specializing in the end-to-end development and commercialization of therapies that arm the immune system against a wide range of diseases including cancer and infectious disease. Our newly focused discovery efforts enhance our ability to support in-house development and nomination of biologics for our preclinical and clinical development efforts. Furthermore, our Scorpion Biological Services, Inc. ("Scorpion") subsidiary enables us to enhance efficiency and decrease our dependence on third-party contract research and development biomanufacturing organizations (CDMO) as we advance into early and late-stage clinical trials and progress our research, development, and commercial pipeline. Finally, our anticipated acquisition of Elusys Therapeutics, Inc. supports our ability to develop critical therapeutic innovations such as RapidVax® for the biodefense sector. These efforts reinforce our goal of decreasing the time and increasing the efficiency of drug development to accelerate the delivery and commercialization of novel immune activating therapies.

Our gp96 platform and RapidVax® platforms are designed to leverage the ability of gp96 to constitutively transport predefined antigens of interest to antigen presenting cells (APCs) that in turn stimulate an antigen-specific immune response that includes B cells, CD4+ T-cells, and cytotoxic CD8+ T-cells. HS-110 (viagenpumatucel-L), an allogeneic ("off-the-shelf") therapy, is our lead gp96 asset having completed Phase 2 enrollment of a non-small cell lung cancer (NSCLC) clinical trial. HS-130, another gp96 platform asset, is engineered to express the extracellular domain of OX40 ligand as a fusion protein (OX40L-Ig) to enhance T-cell expansion and memory cell formation. The safety of HS-130 is being evaluated in a Phase 1 solid tumor trial with findings to support the development of our RapidVax platform.

RapidVax is designed as a programmable vaccine expressing gp96-Ig and OX40L-Ig that can be manufactured in bulk, stockpiled, and rapidly customized upon identification of a biological threat to enable an accelerated time to clinic and to harness shared development, clinical safety, and manufacturing synergies. We have also formed a Biothreat Advisory Board to aid in advancing these biodefense initiatives.

Our Death Receptor 3/TNF receptor superfamily member 25 (DR3/TNFRSF25) platform is focused on the development of agents targeting this cellular receptor. In the absence of a danger or activating signal, co-stimulation of DR3 on T-cells results in the selective expansion of immunosuppressive Tregs that can reduce inflammation. Conversely, co-stimulation of DR3 on T-cells in the presence of a danger or activating signal (arising from injury, infection, or cancer) promotes the expansion of inflammatory effector T-cells that play a critical role in mediating anti-tumor and anti-pathogen responses. We believe therapeutic targeting of this pathway has the potential to shift the balance between immunosuppression and

inflammation and therefore restore stability to the immune system. PTX-35, a monoclonal antibody, is under evaluation in an open-label, dose escalation, Phase 1 clinical trial assessing safety and tolerability in patients with advanced solid tumors refractory to, or otherwise ineligible for standard of care.

Recent Developments

On December 20, 2021, we entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with our wholly owned subsidiary ("Merger Sub"), Elusys Therapeutics, Inc., a Delaware corporation ("Elusys") and Fortis Advisors LLC, pursuant to which, subject to certain conditions, we will acquire Elusys through the merger (the "Merger") of Merger Sub with Elusys. Following the closing of the Merger, Elusys will become a wholly owned subsidiary. Elusys is a company focused on the commercialization of ANTHIM® (obiltoxaximab), which is a monoclonal antibody antitoxin for the "Category A" biological warfare and bioterrorism threat anthrax designed to combat a potential anthrax attack. Elusys has key expertise in the development of biodefense agents having received over $250M of non-dilutive advanced- development contracts from National Institutes of Health (NIH), Department of Defense (DoD), and the Biomedical Advanced Research and Development Authority (BARDA) to support the development of Anthim. To prepare for the possibility of the use of *Bacillus anthracis* as a biological weapon, the U.S. government acquires and maintains equipment and medical countermeasures for anthrax treatment and prevention as part of CDC's Strategic National Stockpile (SNS). The SNS is a national repository of large quantities of medicines, vaccines, and other medical supplies stored in strategic locations around the nation. Anthim has also been delivered to the US Strategic National Stockpile ("SNS") as the result of a successful, multi-year partnership with the U.S. government. Following clearance by the U.S. Food and Drug Administration ("FDA") in March 2016 and orphan drug exclusivity for the treatment of inhalational anthrax due to *Bacillus anthracis* inhalation in combination with antibiotics, and as a prophylaxis when alternative therapies are not available or are not appropriate. In July 2020, Health Canada approved ANTHIM's New Drug Submission (NDS) for the treatment of inhalation anthrax. ANTHIM has also received marketing approval in the E.U. and the U.K., under the trade name of Obiltoxaximab SFL. The acquisition of Elusys has not been completed and is subject to several conditions.

Anthrax is a disease caused by *Bacillus anthracis*. While it is primarily a disease of animals, cases of anthrax in humans occur through contact with infected animals or animal products or through intentional spread of *Bacillus anthracis* spores as a biowarfare or bioterrorism agent. Anthrax is regarded as a top ("Category A") biological warfare and bioterrorism threat for as untreated inhalational anthrax has a high fatality rate, *Bacillus anthracis* is widely available and have been used in the past as a biological weapon, and multi-drug resistant (MDR) *Bacillus anthracis* is recognized by Public Health Emergency Medical Countermeasures Enterprise as a high-priority threat. Anthim inhibits the binding of PA to its cellular receptors, preventing the intracellular entry of the anthrax lethal factor and edema factor, the enzymatic toxin components responsible for the pathogenic effects of anthrax toxin.

Material Terms of the Merger

Pursuant to the Merger Agreement, as merger consideration ("Merger Consideration") we (i) agreed to pay the current equity holders of Elusys (the "Sellers") $3,000,000 at Closing; and (ii) agreed to pay the Sellers $2,000,000, subject to reduction based on the cash balance of Elusys at Closing and other purchase price reductions specified in the Merger Agreement, at the same time as the initial pass through revenue is distributed to the Sellers as described below and (iii) earn out payments for a period of 12 years from the date of Closing equal to 10% of the gross dollar amount of payments received during each one year period during such twelve year period with respect to any sale, license or commercialization anywhere in the world of Anthim that either: (a) occurs during the first nine years after the Closing Date in any respect; or (b) occurs thereafter pursuant to any contract, agreement, commitment or order that is placed, granted, awarded or entered into during the first nine years after the Closing Date.

In addition, Elusys is expected to receive additional revenue from the future fulfillment of an existing U.S. Government contract and we have agreed to fulfill the future obligations of Elusys under such contract and pass through and distribute to the Sellers the revenue that is received under such contract minus the costs associated with such fulfillment obligations, subject to certain adjustments to the Merger Consideration specified in the Merger Agreement, including income taxes payable with respect to such payments. The Merger Agreement further provides that eighty percent of any amounts paid

to and received by Elusys after the Closing and prior to June 30, 2023 with respect to the sale of 1,500 pre-filled vials of Anthim shall be paid to the Sellers, subject to certain adjustments specified in the Merger Agreement.

At Closing, we also agreed to contribute to the payment of 50% of certain Elusys lease termination and employee severance payments. We also agreed to use commercially reasonable efforts to maintain, finance, operate and promote Anthim and maintain the existing government contract and to continue to operate the Elusys business so as to allow the Sellers to receive the Merger Consideration.

The Merger Agreement contains customary representations, warranties and covenants of Heat, Elusys and the Merger Sub. The consummation of the Merger was subject to the satisfaction or waiver of certain conditions, including Elusys obtaining a requisite stockholder vote to approve the Merger, which approval was obtained. Subject to certain customary limitations, the Sellers have agreed to indemnify us and our officers and directors against certain losses related to, among other things, breaches of Elusys' representations and warranties, certain specified liabilities and the failure to perform covenants or obligations under the Merger Agreement.

A special committee of Heat's Board of Directors negotiated and approved the transaction and Cassel Salpeter & Co. provided a fairness opinion in connection with the transaction. Cassel Salpeter served as financial advisor to the special committee of Board of Directors.

Elusys was formed in 1998 by Jeff Wolf, our President, Chief Executive Officer and Chairman of the Board of Directors, who directly and through affiliated entities owns approximately 1.2% of the outstanding stock of Elusys, in the form of common stock, which is subordinate in terms of distributions to the Elusys preferred stock. Due to the potential conflict of interest, we formed a Special Committee of its Board of Directors to review and negotiate the Merger Agreement. However, pursuant to the terms governing the Elusys preferred stock, the preferred stockholders of Elusys will receive all of the initial $5 million of Merger Consideration and all of the net payments from the $31 million of revenues related to fulfillment of the existing SNS contract. While the amount of earn out payments, if any, to be made over the 12 year period following closing is very uncertain, it also presently seems likely that most if not all of such payments will also be paid to the preferred stockholders of Elusys under the terms of such preferred stock.

The foregoing summary of the Merger Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Merger Agreement that is filed herewith as Exhibit 2.1.

Elusys Intellectual Property

Elusys has an exclusive, fully paid up, worldwide patent license, dated June 30, 2003, from the Board of Regents of the University of Texas which grants Elusys the right to use for the manufacture, offer and sale of antibodies that bind immunologically to anthrax antigens under the patent rights held by the University of Texas under U.S. patent application entitled "Neutralization of the Anthrax Toxin", serial number 10/288,269 filed on November 5, 2001 (and subsequently issued by the U.S. Patent and Trademark Office on November 4, 2008, serial number 7,446,182) and the U.S. patent application entitled "Antibodies With Increased Affinities For Anthrax Antigens", serial number 10/620,049 filed om July 15, 2003 (and subsequently issued by the U.S. Patent and Trademark Office on March 8, 2011, serial number 7,9902,344). The term of agreement continues until all patent rights have expired, unless terminated automatically due to bankruptcy or insolvency of Elusys or by mutual written agreement.

Elusys is the assignee of the U.S. patent application entitled "Antibodies that bind B. anthracis exotoxin, formulations thereof, and methods of use", serial number 11/904,882 filed on September 28, 2007 (and subsequently issued by the U.S. Patent and Trademark Office on January 10, 2012, serial number 8,093,360) and the U.S. patent application entitled "Methods of preventing or treating anthrax using anti-anthrax antibodies", serial number 13/076,082 filed on March 30, 2011 (and subsequently issued by the U.S. Patent and Trademark Office on December 31, 2013, serial number 8,617,548).

Technology Platforms

gp96 Platform

Our proprietary gp96 platform leverages the adjuvant (immune stimulatory) properties of the heat shock protein gp96 to induce the immune system's own response against cancer and infectious disease. gp96 naturally chaperones activation peptides (antigens) to antigen-presenting cells (APCs), such as dendritic cells, under stress conditions such as infection and cell death. Extracellular gp96 can stimulate innate immune toll-like receptors 2 and 4 on APCs to promote activation and subsequent processing and presentation of chaperoned antigens to T-cells. Our platform is designed to exploit the chaperoning activity of gp96 to constitutively transport predefined antigens of interest to APCs that in turn stimulate an antigen-specific immune response that includes B cells, $CD4^+$ T-cells, and cytotoxic $CD8^+$ T-cells.

In the context of cancer, this platform is designed to activate and expand tumor antigen specific "killer" T-cells to destroy a patient's cancer. By turning immunologically "COLD tumors HOT," we believe our platform can become an essential component of the immuno-oncology regimen to enhance the effectiveness and durability of checkpoint inhibitors and other cancer therapies, thereby improving outcomes for those patients less likely to benefit from checkpoint inhibitors alone. We believe this is a highly differentiated approach as our platform can deliver a broad range of tumor antigens that are previously unrecognized by the patient's immune system and that have the potential to generate a multivalent response to address tumor heterogeneity.

Our leading cancer vaccine therapeutics are replication incompetent, "off-the-shelf", allogenic cell-based therapies that are locally delivered into the skin and can be administered with a variety of immuno-modulators to enhance a patient's immune response. Unlike many other "patient specific" or autologous immunotherapy approaches, this fully allogeneic, "off-the-shelf" approach provides a means to quickly administer the biotherapeutic without the need to extract and expand blood or tumor tissue from individual patients or create individualized treatment based on the patient's haplotype. Our gp96 product candidates are produced from allogeneic cell lines expressing a broad repertoire of established tumor-specific antigens. Because each patient receives the same treatment, we believe that our immunotherapy approach offers superior speed to initiation, logistics, manufacturing efficiencies, and importantly, cost benefits, compared to "personalized" precision medicine approaches.

Besides its utility in oncology, our gp96 platform has been shown to activate the human immune system to combat infectious diseases. Our collaborators have laid a solid foundation by engineering different pathogenic antigens into the platform. Previous preclinical studies using our gp96 platform includes SIV/HIV, Malaria, Zika and COVID-19.

About ComPACT®

ComPACT is designed to further enhance our gp96 platform by facilitating antigen-driven T-cell activation and specific co-stimulation in a single product. By delivering the gp96 heat shock protein and a T-cell co-stimulatory fusion protein (OX40L) as a single therapeutic, this approach has the potential to simplify combination immunotherapy development. This dual design has several potential advantages including: (a) enhanced activation of antigen-specific CD8+ T-cells; (b) boosting the number of antigen-specific CD8+ and CD4+ T-cells compared to OX40L alone; (c) stimulation of durable T-cell memory; (d) the differentiation of T follicular helper cells that facilitate antibody production by B cells; (e) demonstration of less toxicity, as the source of associated antigens and co-stimulator are supplied at the same time locally in the draining lymph nodes, which drives targeted, specific immunity rather than throughout the body; and (f) simplification of combination immunotherapy versus systemic co-stimulation with conventional monoclonal antibodies (mAbs).

RapidVax® Platform

Unveiled at the 2021 World Vaccine & Immunotherapy Antiviral Congress, RapidVax® is a flexible "plug-and-play" vaccine platform designed to enable an accelerated response to a wide variety of biological threats and is built on the foundation of our learnings from our *various gp96* programs (noted above). RapidVax leverages our vast experience developing gp96-based vaccines and couples the immune-activating properties of heat shock protein gp96 and the T-cell co-stimulator OX40L with a flexible antigen expression system to promote antigen-specific T-cell activation, the

generation of long-lasting memory cells, and neutralizing antibody production via the interaction of T follicular helper cells with B cells.

RapidVax is designed to utilize a common unprogrammed vaccine base that can be manufactured in bulk, stockpiled, and rapidly customized upon identification of a biological threat to enable an accelerated time to clinic and to harness shared development, clinical safety, and manufacturing synergies.

This platform has several potential advantages including but not limited to: (a) potential stockpiling capability designed to accelerate time to clinic by harnessing prior optimizations in development, safety, and manufacturing; (b) potential customization with multiple full length target antigens to increase potential protection against pathogen variants; (c) enhanced activation of antigen-specific CD8+ T-cells; (d) boosting the number of antigen-specific CD8+ and CD4+ T-cells compared to OX40L alone; (e) stimulation of durable T-cell memory; and (f) the differentiation of T follicular helper cells that facilitate antibody production by B cells.

DR3/TNFRSF25 Platform

Our Death Receptor 3/TNF receptor superfamily member 25 (DR3/TNFRSF25) platform is focused on the development of agents targeting this cellular receptor. DR3 recognizes the cytokine TNF-like ligand 1A (TL1A) secreted by several immune cell types including dendritic cells, monocytes, macrophages, and plasma cells. In the absence of a danger or activating signal, co-stimulation of DR3 on T-cells results in the selective expansion of immunosuppressive Tregs that can reduce inflammation. Conversely, co-stimulation of DR3 on T-cells in the presence of a danger or activating signal (arising from injury, infection, or cancer) promotes the expansion of inflammatory effector T-cells that play a critical role in mediating anti-tumor and anti-pathogen responses. We believe therapeutic targeting of this pathway has the potential to shift the balance between immunosuppression and inflammation and therefore restore stability and balance to the immune system.

Agonists of the DR3 pathway have demonstrated benefit in several non-oncology disease models including rheumatoid arthritis, diabetic retinopathy, allergic lung inflammation, inflammatory bowel disease, infectious disease, and hematopoietic stem cell transplant. Conversely, DR3 agonism in the presence of tumor antigens and combined with our HS-110 and HS-130 immunotherapies or an anti-PD-1 checkpoint inhibitor leads to a reduction in the suppressive activity of Tregs, compromised Treg stability, increased Treg plasticity, and an increased percentage of inflammatory CD4+ Th1, CD4+ Th17, CD8+ effector T-cells that delay disease progression in solid tumor models.

We believe these dynamic immunomodulatory properties of the DR3 pathway make it a compelling therapeutic target with various potential medical applications for either inducing inflammatory responses or restoring stability to the immune system. To date, we are the only known company with a disclosed program targeting DR3 for use in immuno-oncology, with a broad, pioneering intellectual property estate.

Platform Assets: gp96 Platform

HS-110 (viagenpumatucel-L): Clinical Stage

Based on our gp96 platform technology, we have developed the product candidate HS-110 (viagenpumatucel-L) as a potential treatment for patients with advanced non-small cell lung cancer (NSCLC). HS-110 is an allogenic “off-the-shelf” cellular vaccine derived from a lung adenocarcinoma cancer cell line and genetically modified to secrete a wide range of cancer-associated antigens bound to the immunostimulatory chaperone gp96. This approach is designed to stimulate and facilitate uptake of these antigens by professional antigen presenting cells (APCs), which in turn activate a broad, T-cell medicated immune response against a patient’s cancer. For additional technology details, please review the gp96 platform section above.

We have completed the enrollment of our Phase 2 trial evaluating the safety and efficacy of HS-110 in combination with either nivolumab (Opdivo®), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, or Merck’s anti-PD1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®), for the treatment of patients with advanced NSCLC. Eligible patient

populations included individuals in a second line or greater setting, or with pembrolizumab in a front-line maintenance setting.

On February 9, 2021, we announced positive interim data from the Phase 2 trial. A substantial survival benefit was observed in a cohort of previously treated, checkpoint inhibitor naïve patients with advanced NSCLC (Cohort A, N = 47). A median overall survival (mOS) of 24.6 months was observed with a median follow-up time of 19.4 months and a one-year survival rate of 61.7% (Cohort A). For historical reference, the BMS CheckMate 057 study evaluating a similar population of previously treated, advanced NSCLC patients who received nivolumab as a single agent reported a mOS of 12.2 months and a one-year survival rate of 50.7%.

For NSCLC patients undergoing disease progression following checkpoint inhibitor therapy, there are a limited number of therapeutic options, with chemotherapy reporting a mOS of 6.8 to 9.0 months based on the literature. As of February 9, 2021, in our Phase 2 study, we observed that HS-110 and nivolumab combinatorial treatment of NSCLC patients exhibiting disease progression following previous PD-(L)1 therapy resulted in a mOS of 11.9 months with a median follow-up time of 11.9 months (Cohort B, N = 68).

As of this February 9, 2021 data cut, 30% of the patients in Cohort A and 26% of the patients in Cohort B were still alive. HS-110 has a favorable safety profile with no treatment-related serious adverse reactions. In addition, review of immune-related adverse events reported in the study raised no safety concerns. The data to date demonstrate that combination of HS-110 and nivolumab treatment is well-tolerated.

Further subset analysis was reported on May 20, 2021 when we announced that an abstract entitled “Interim results of viagenpumatucel-L (HS-110) plus nivolumab in previously treated patients (pts) with advanced non-small cell lung cancer (NSCLC) in two treatment settings” had been accepted for poster presentation at the 2021 ASCO Annual Meeting. Announced on June 4, 2021 these findings were presented by Roger B. Cohen, MD, Professor of Medicine at the University of Pennsylvania Perelman School of Medicine at the meeting. Analysis of a subset of Cohort A patients that experienced an injection site reaction (ISR+) revealed increased progression free survival (PFS) and median overall survival (mOS) (hazard ratio [HR]=0.43, p=0.01; HR=0.23, p<0.001). A longer mOS was also observed in patients with PD-L1 expression level ≥ 1% (HR=0.25, p=0.02). Similarly, an increased mOS was also reported in ISR+ patients in Cohort B (HR=0.48, p=0.03).

Due to the large number of patients expected to be enrolled in any pivotal clinical trial of HS-110, we do not anticipate initiating a pivotal trial of HS-110 until after we have secured additional potential financing via a strategic partnership.

HS-130: Clinical Stage

We have completed enrollment of our first-in-human Phase 1 open label dose-escalation study evaluating the safety of HS-130 in combination with HS-110 for the treatment of advanced solid tumors. HS-130 is designed to test our *ComPACT*™ technology approach by secreting the T-cell co-stimulatory fusion protein OX40L to support the expansion of T-cells and the generation of immunological memory. The findings of this program are contributing to the development of our RapidVax platform discussed above.

Platform Assets: RapidVax®

RapidVax® Base Cell: Preclinical Stage

The RapidVax® base cell and core technology are in preclinical development. Combing the immune-activating properties of heat shock protein gp96 and the T-cell co-stimulator OX40L with a customizable antigen expression system, we are evaluating several infectious and emerging diseases as vaccine candidates. RapidVax is designed to utilize a common unprogrammed vaccine base that can be manufactured in bulk, stockpiled, and rapidly customized upon identification of a biological threat to enable an accelerated time to clinic and to harness shared development, clinical safety, and manufacturing synergies. Further details regarding the RapidVax technology can be found in the “RapidVax Platform” section above.

Platform Assets: DR3/TNFRSF25 Platform

PTX-35: Clinical Stage

PTX-35 is a potential first-in-class selective agonist of DR3. This humanized monoclonal antibody is designed to harness antigen specific immune activation and tolerance mechanisms associated with the DR3 pathway to reprogram immunity and provide a long-term, durable clinical effect. In the absence of a danger or activating signal, co-stimulation of DR3 on T-cells results in the selective expansion of immunosuppressive Tregs that can reduce inflammation. Conversely, co-stimulation of DR3 on T-cells in the presence of a danger or activating signal (arising from injury, infection, or cancer) promotes the expansion of inflammatory effector T-cells that play a critical role in mediating anti-tumor and anti-pathogen responses. Further details regarding the importance of the DR3 pathway in regulating immune responses can be found above in the corresponding platform section.

Preclinical studies demonstrate that when combined with HS-110 and HS-130 immunotherapies or an anti-PD-1 checkpoint inhibitor, PTX-35 has the potential to enhance antigen specific T-cell activation to eliminate tumor cells. With this consideration, we are enrolling an open-label, dose escalation, Phase 1 clinical trial evaluating the safety and tolerability of PTX-35 intravenous administration in patients with advanced solid tumors refractory to, or ineligible for, or who refuse available standard of care. As of June 2020, we treated the first patient and are evaluating escalating dose levels of PTX-35 until an optimal immunological dose or maximum tolerated dose is established to support potential Phase 2 planning. Exploratory analyses include clinical benefit and immunological effects of PTX-35. This trial is supported by a $15.2 million grant from the Cancer Prevention and Research Institute of Texas.

PTX-35 has also been reported as a potent regulatory T-cell (Treg) expander in the absence of a danger or activating signal. Mouse surrogate of PTX-35 (i.e., human CDRs 1-3, but mouse Ig backbone), has shown activity in mouse models of corneal allograft, beta-islet transplantation, bone marrow transplantation, auto/inflammatory models of experimental autoimmune encephalitis (EAE), colitis and asthma. Furthermore, on January 12, 2022 we announced in collaboration with Dr. James Shapiro at University of Alberta that a surrogate mouse version of PTX-35 (mPTX-35) could expand regulatory T-cells *in vivo* to successfully prevent the rejection of allogeneic transplanted beta-isle T-cells in an animal model of type-1 diabetes.

We are currently evaluating the clinical application for using PTX-35 to expand regulatory T-cell subsets for the treatment of various inflammatory diseases and/or conditions where regulatory T-cells are defective or required to restore immune stability.

Key Capabilities

Our Discovery Capabilities: Skunkworx Bio, Inc.

In November 2018, we formed the discovery subsidiary Skunkworx Bio, Inc. (formerly known as Delphi Therapeutics, Inc.) to support in-house nomination of biologics for preclinical and clinical development. Our approach utilizes “Pocket Biologics” derived from diverse proprietary antibody and small protein libraries to identify and differentiate pharmacologically active “HotSpot” sites on proteins relevant to disease. Coupled with the integration of computational and bioinformatic analysis, the goal is to “improve” candidate selection and accelerate validation of innovative therapeutics and biodefense assets from discovery into preclinical development.

Our Bioanalytic, Process Development, and Biomanufacturing Capabilities: Scorpion Biological Services, Inc.

In November 2018, we formed the subsidiary Scorpion Biological Services, Inc. (“Scorpion”) (formerly known as Scorpion Biosciences, Inc.), to focus on developing bioanalytic, process development and biomanufacturing capability to support our biotherapeutics and discovery pipeline. Excess biomanufacturing capacity will also be offered to third parties as a fee-for-service model. This expansion is part of a company-wide-growth strategy to enhance efficiency and decrease our dependence on third-party contract research and development biomanufacturing organizations (CDMO) as we advance into late-stage clinical trials and translate our research, development, and commercial pipeline.

Scorpion Biological Services is focused on cell- and gene-based therapies and large molecule biologics. Once the facility described below is operational, Scorpion plans to provide a broad array of biologics manufacturing, analytical and R&D services, offering services using American-made equipment, reagents, and materials. Scorpion plans to couple cGMP biomanufacturing and quality control expertise with cutting edge capabilities in immunoassays, molecular assays, and bioanalytical methods to support the advancement of our development and commercial programs.

We have signed a lease to occupy a 20,144 square foot facility in San Antonio, Texas where we plan to conduct services and are currently in the process of building the biomanufacturing facility.

Operations at the facility are projected to commence in the second quarter of 2022, and we expect to utilize a portion of this production capacity by immediately transitioning our outsourced manufacturing and development to Scorpion. Fee-for-service contracting with be offered to external customers.

Our Current Biodefense Capabilities:

RapidVax®: Preclinical Stage

RapidVax® is being designed as a flexible "plug-and-play" vaccine platform designed to leverage our vast experience developing gp96-based vaccines and couples the immune-activating properties of heat shock protein gp96 and the T-cell co-stimulator OX40L with a flexible antigen expression system to promote antigen-specific T-cell activation, the generation of long-lasting memory cells, and neutralizing antibody production via the interaction of T follicular helper cells with B cells. RapidVax is designed to utilize a common unprogrammed vaccine base that can be manufactured in bulk, stockpiled, and rapidly customized upon identification of a biological threat to enable an accelerated time to clinic and to harness shared development, clinical safety, and manufacturing synergies. Further details regarding RapidVax can be found in the section "Platform Assets: RapidVax" above.

Biothreat Advisory Board

In August 2021, we announced the formation of our Biothreat Advisory Board to support the development of our biosecurity/biodefense initiatives. The advisory board includes David Lasseter, Former Deputy Asst. Sec. of Defense for Countering Weapons of Mass Destruction, Andrew Webber, Former Asst. Sec. of Defense for Nuclear, Chemical & Biological Defense Programs, Jack Kingston, Former US Representative, Secretariat of the Alliance for Biosecurity (current), Gregor Koblentz, PhD, Professor of Biodefense at George Mason University, Expert on Chemical and Biological Weapons, and Former US Senator (AR) Mark Pryor. This panel was assembled to provide ongoing guidance on the development and commercialization of our biodefense assets and platforms.

Anthim® (obiltoxaximab): Commercially Approved

Anthim® (obiltoxaximab) is a best-in-class monoclonal antibody antitoxin for the "Category A" biological warfare and bioterrorism threat anthrax. Anthim received FDA approval and orphan drug exclusivity in 2016 for the treatment of inhalational anthrax, in combination with antibiotics, and as a prophylaxis when alternative therapies are not available or are not appropriate. Anthim was also approved in 2020 as the only licensed anthrax antitoxin treatment in the EU, UK, and Canada. We will add Anthim to our current biodefense capabilities upon consummation of the pending acquisition of Elusys.

Oncology and Biodefense Market and Current Treatments

Solid Tumors and Non-Small Cell Lung Cancer (NSCLC)

The American Cancer Society (ACS) estimates that approximately 1.9 million people in the United States will be diagnosed with cancer and ~609,360 cancer-related deaths will occur in 2022. Notably, this number includes approximately 350 deaths per day from lung cancer, the leading cause of cancer death and the second-most diagnosed cancer in the U.S (approximately 236,740 or 12% of all cases). Approximately 82% of all lung cancer is NSCLC.

Despite continuous advances in cancer screening and the adoption of promising therapies such as immune checkpoint inhibitors (CPIs), there remains a significant unmet medical need as published studies demonstrate only a minority of single agent treated patients benefit with prolonged overall survival. Poor response to CPIs is thought to be partly attributable to properties of the tumor microenvironment and the concern that even if the "brake" set by immune checkpoints is released through CPI therapy, optimal antitumor immune responses may not be elicited due to a lack of antigen exposure. These observations have prompted the development of vaccines against cancer antigens that can generate high frequencies of tumor-specific T-cells. We believe the idea of dual immunotherapy with cancer vaccines and CPIs has garnered particular interest based on the hypothesis that the elevated frequencies of tumor-specific T-cells generated by cancer vaccines can be expanded and protected from attenuation through blockade of T-cell checkpoint receptors.

To date, pembrolizumab (KEYTRUDA®), Merck's anti-PD1 checkpoint inhibitor, atezolizumab (TECENTRIQ®) Roche Genetech's anti-PD-L1 checkpoint inhibitor, and cemiplimab (LIBTAYO®), Regeneron's anti-PD-1 inhibitor, are approved CPIs for the treatment of first-line NSCLC. Per the CPI Global Market Report 2021 the global market for CPIs is anticipated to from approximately $18 billion in 2021 to an estimated $39.8 billion in 2025. iHealthcareAnalyst, Inc estimates the global market for NSCLC therapeutics will grow at a CAGR of 11.4% to reach $22.4 billion by 2027 with the PD-1/PD-L1 inhibitors segment expected to grow at the fastest rate during forecast period. It is also noted that immunotherapy combinations with chemotherapy, radiation therapy, or novel immunomodulatory agents are currently being examined with the hope of achieving higher response rates and improving overall survival rate.

We believe that our novel allogenic "off-the-shelf" cancer vaccine HS-110 is well-positioned as a Phase 2 clinical program with the potential for combination therapy with approved CPIs for the treatment of NSCLC. Further details regarding HS-110 can be found above in the platform asset section.

We believe that our DR3 agonist PTX-35 has the potential in the presence of activating signals (such as cancer antigens) to drive the expansion of anti-tumor lymphocytes and are currently investigating potential solid tumor applications in our Phase I clinical trial. Further details regarding PTX-35 can be found above in the platform asset section.

Strategy

Our objective is to become a fully integrated biopharmaceutical company specializing in the end-to-end discovery, development and commercialization of therapies that arm the immune system against a wide range of diseases, including cancer and infectious disease. Through the formation of our subsidiary Skunkworx Bio, Inc, we have increased our ability to support in-house nomination of biologics for our preclinical and clinical development. Furthermore, the establishment of our subsidiary Scorpion Biological Services, Inc is part of a company-wide-growth strategy to enhance efficiency and decrease our dependence on third-party contract research and development biomanufacturing organizations (CDMO) as we advance into late-stage clinical trials and translate our other research and development into a commercial pipeline. Finally, the planned acquisition of Elusys Therapeutics, Inc and the addition of the FDA-approved anthrax antitoxin Anthim® (obiltoxaximab) as well as expertise in government funding for development and delivery should support our ability to develop critical therapeutic innovations such as RapidVax® for the biodefense sector. These proceedings reinforce our goal of decreasing the time and increasing the efficiency of drug development to accelerate the delivery of novel immune activating therapies.

We believe the effective management of cancer will involve multiple agents and that the assets of our gp96 and DR3/TNFRSF25 platforms have the potential to work synergistically with approved immunotherapies, such as checkpoint inhibitors, to re-stimulate or enhance the immune system's own anti-tumor response. With this consideration, we are evaluating the potential of the gp96 platform allogenic "off-the-shelf" immunotherapy HS-110 in a Phase 2 NSCLC trial to stimulate tumor-specific T-cell in combination with anti-PD-1 therapies and potentially increase overall survival. The DR3 agonist PTX-35 has been reported to promote the expansion of effector CD8+ T-cells in cancer models in the presence of a danger (activating signal) and is in a Phase 1 solid tumor clinical trial to assess safety and tolerability.

We believe the DR3 pathway has potential for the management of non-oncology immune disorders as evidenced by literature demonstrating DR3-mediated benefit in several disease models including rheumatoid arthritis, diabetic retinopathy, allergic lung inflammation, inflammatory bowel disease, infectious disease, and hematopoietic stem cell transplant.

The key elements of our strategy are:

- *Establish a fully integrated biopharmaceutical company specializing in end-to-end delivery of immune stimulating therapies:* With the formation of our subsidiaries Skunkworx Bio, Inc and Scorpion Biological Services Inc., we have created a drug development ecosystem designed to fuel innovation, from discovery to commercialization, with minimal reliance on external vendors. This capability offers the potential to translate our discoveries into therapeutics with increased efficiency and quality and without compromising our agility to pursue new innovations.

- *Maximize commercial opportunities for Anthim® (obiltoxaximab) upon the consummation of our pending acquisition of Elusys:* We believe that Anthim will continue to be a critical biodefense asset for stockpiling by the CDC's Strategic National Stockpile (SNS) and of potential interest for increasing biosecurity preparedness in commercially approved ex-US ally territories such as the EU, UK, and Canada. Upon the acquisition of Elusys, we intend to be opportunistic in seeking strategic partnerships that maximize economic potential of this asset. We are in the process of completing the tech transfer of this asset to Scorpion for future biomanufacturing; Anthim has previously been manufactured by an external vendor.

- *Maximize commercial opportunities for Scorpion Biological Services, Inc:* We plan to launch Scorpion Biological Services, Inc. as a contract research and development biomanufacturing organization (CDMO) focused on developing bioanalytic, process development and biomanufacturing capabilities to support our biotherapeutics and discovery pipeline. We will be opportunistic in offering biomanufacturing capacity to third parties as a fee-for-service model.

- *Develop and obtain regulatory approval for our product candidates*: We have completed enrollment of the HS-110 trial in combination with either nivolumab or pembrolizumab to treat patients with advanced NSCLC. We have initiated enrollment of our Phase 1 trial of HS-130 in combination with H-110 for treatment of solid tumors and our Phase 1 trial of PTX-35 for the treatment of solid tumors. Beyond these trials we plan to initiate new clinical trials of combined immunotherapy agents.

- *Maximize commercial opportunity for our technology platforms*: Our technologies support the development of product candidates targeting large markets with significant unmet medical needs. For each of our platform assets, we seek to maximize the economic potential of any future U.S. or international commercialization efforts.

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

- *Further expand our broad patent portfolio*: We have made a significant investment in the development of our patent portfolio to protect our technologies and programs, and we intend to continue to expand our portfolio. We have obtained exclusive rights to six different patent families directed to therapeutic compositions and methods related to our platform and preclinical development programs for cancer, and have filed additional patent applications that are owned by us. The gp96 patent portfolio comprise more than 35 granted patents and 40 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 65 granted U.S. and foreign patents and approximately 25 U.S. and foreign patents are pending.

- *Manage our business with efficiency and discipline*: We believe we have efficiently utilized our capital and human resources to develop and acquire our product candidates and programs and create a broad intellectual property portfolio. These resources have formed our drug development ecosystem. 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 Therapeutic, Inc's $15.2 million CPRIT Grant.* To develop our technologies and compounds more fully, 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 external partners, including academic key opinion leaders and retention of lobbyists, to support the development of our pipeline programs. We also intend to continue to evaluate opportunities and, as appropriate, acquire or license technologies that meet our business objectives.

Pelican Acquisition

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

Pelican is a biotechnology company focused on the development and commercialization of monoclonal antibody and fusion protein-based therapies that are designed to activate the immune system. In exchange for 80% of the outstanding capital stock of Pelican on a fully diluted basis, we paid to the Pelican Stockholders that executed the Stock Purchase Agreement (the "Participating Pelican Stockholders") an aggregate of $0.5 million minus certain liabilities (the "Cash Consideration"), and issued to the Participating Pelican Stockholders 19,015 shares of our restricted common stock representing 4.99% of the outstanding shares of our common stock on the date of the initial execution of the Purchase Agreement (the "Stock Consideration"). The Pelican Stockholders that sold their shares in Pelican to us (the "Participating Pelican Stockholders") included Jeffrey Wolf, our Chief Executive Officer and a director, John Monahan and Edward Smith, two of our directors, the Chairman of our Scientific Advisory Committee at the time of the closing and/or entities controlled by them. During the year ended December 31, 2018, the Cash Consideration of approximately $0.3 million was distributed to the Participating Pelican Stockholders and the remainder of approximately $0.2 million for certain Pelican liabilities not satisfied was retained by us and recognized as other income in the Consolidated Statements of Operations and Comprehensive Loss. During the year ended December 31, 2020, we distributed to the Participating Pelican Stockholders $2.0 million upon dosing of the first patient in our Phase 1 trial of PTX-35, of which approximately of 22% was distributed to our executive officers and directors who are Participating Pelican Stockholders.

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

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

On June 22, 2020, the Company achieved the first milestone of $2.0 million when it dosed the first patient in the first Phase 1 clinical trial of PTX-35.

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

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

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

CPRIT Grant

In May 2016, Pelican was awarded a $15.2 million CPRIT Grant from CPRIT for development of Pelican's lead product candidate, PTX-35. The CPRIT Grant is expected to allow Pelican to develop PTX-35 through a 40-50 patient Phase 1 clinical program. The CPRIT Grant is subject to customary CPRIT funding conditions including a matching funds requirement where Pelican will match $0.50 for every $1.00 from CPRIT. Consequently, Pelican is required to raise $7.6 million in matching funds over the life of the project.

As of December 31, 2021, CPRIT has provided $13.7 million of the total $15.2 million grant. The remaining $1.5 million will be awarded, on a reimbursement basis, after we have fulfilled grant requirements and the grant has been approved to be finalized, rather than in advance of expending the funds as in the prior grant years. As of December 31, 2021, we have provided approximately $7.6 million which was used to satisfy Pelican's matching fund obligation under the first five years of the CPRIT Grant.

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

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

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies; preserve our trade secrets and exclusive rights in our unique biological materials; and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the strongest intellectual property protection possible for our current product candidates and any future product candidates and our subsidiaries', 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.

Our and our subsidiaries' programs are supported by growing patent estates that are comprised of intellectual property owned by us and our subsidiaries', or exclusively licensed from UM. *ImPACT*®, *ComPACT*™, PTX-35, and next generation DR3/TNFRSF25 modulators are protected by issued patents and various pending patent applications. In total, Heat holds approximately 35 granted U.S. and foreign patents and approximately 40 U.S. and foreign patents pending. In total, Pelican holds approximately 65 granted U.S. and foreign patents and approximately 25 U.S. and foreign patents are pending.

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

Heat's *ComPACT*™ technology is covered by US Patent Nos. 10,046,047 and 10,780,161 and a series of patents pending in the U.S. and foreign jurisdictions (i.e. Europe, Japan, China, Canada, Australia, Brazil, Mexico, Israel, India, Korea, Russia, Singapore and South Africa) and assigned to Heat. Various recently filed provisional, international (PCT), US, and foreign patent applications assigned to Heat and related to ComPACT™ are also pending and may provide coverage to 2038 to 2042, if granted (not including any patent term adjustments or extensions).

Pelican's PTX-35 and next generation DR3/TNFRSF25 modulators coverage stems from three exclusive license agreements with UM (i.e. "UM03-31 UM05-39" of July 11, 2008; "UMI176" of December 12, 2010, as amended December 7, 2020; 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 novel DR3/TNFRSF25 modulator 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 novel DR3/TNFRSF25 modulator uses in therapies to delay transplant rejections. US Patent No. 9,839,670, with term to 2026 (not including any patent term adjustments or extensions), covers PTX-35 compositions in combination with a tumor antigen. US Patent No. 9,017,679 with term to 2026 (not including any patent term adjustments or extensions), covers methods of using PTX-35, among other things. Recent patent applications assigned to Pelican are intended to provide further compositional coverage for PTX-35. US Patent Nos. 9,982,057 and 10,005,843 provide composition of matter coverage for PTX-35 and have term to 2035 (not including any patent term adjustments or extensions).

License Agreements

The "Modified Heat Shock Proteins-Antigenic Peptide Complex" patent family is licensed pursuant to the terms of an exclusive license agreement that was entered into by Heat in July 2008 and subsequently assigned to our subsidiary Heat Biologics I, Inc. which issued to UM shares representing seven and one-half percent (7.5%) of its common stock, of which UM transferred to Heat in exchange for shares of our common stock in October 2018. The license term lasts until the patent family expires, 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 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 under licensed patent rights.

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

As consideration for the rights granted in each of these three license agreements, Heat Biologics I, Inc. is obligated to pay royalties equal to a percentage (in the low-to-mid single digits) of net sales of products covered by the patent-related rights in the respective license agreements. These royalty rates are subject to reduction if additional license rights from third parties are required to commercialize licensed products. In the event of a sublicense to a third party, Heat Biologics I, Inc. is obligated to pay royalties to UM equal to a percentage of sublicense income. Each of these additional license agreements also provides that the licensee will not have to pay more than the above-noted royalty rates and sublicense fees if more than one license from UM is required to sell products covered by the licensed patent-related rights.

All of the above-described license agreements, as amended, 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, 2025; (2) has not otherwise exercised diligence to bring licensed products to market; or (3) files, or has filed against it, a proceeding under the Bankruptcy Act, is adjudged insolvent, makes an assignment for the benefit of its creditors, or has an unreleased or unsatisfied writ of attachment or execution levied upon it. Upon an uncured material breach of an obligation under any one of the above license agreements by a party, the other party has the right to terminate that agreement upon 90 days' notice or 30 days' notice if the breach relates to payments due to UM. In the event of a termination, Heat Biologics I, Inc. will be obligated to pay all amounts that accrued prior to such termination. Each of the above license agreements also contains other customary clauses and terms as are common in similar agreements between industry and academia, including the licensee's agreement to indemnify UM for liabilities arising out of the negligence of the licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

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

Pelican License Agreements

Under license agreements with UM, Pelican has obtained exclusive rights to six different patent families each directed to therapeutic compositions and methods related to targeting DR3/TNFRSF25/TL1A for the purpose of modulating immune responses. These families comprise approximately 45 granted U.S. and foreign patents, and approximately 30 U.S. and foreign patent applications. These patents and applications cover the United States, Europe and Japan as well as several other countries having commercially significant markets. As partial consideration for the initial two license agreements with UM, Pelican issued UM 300,000 shares of its common stock of which UM transferred to Heat in exchange for shares of our common stock in October 2018.

As consideration for the rights granted under the initial license agreement, UM03-31 and UM05-39 non-oncology, Pelican is obligated to pay UM certain upfront license fees and milestone payments of ((i) $25,000 upon submission of an IND, (ii) $25,000 upon approval of an IND, (iii) $100,000 upon completion of a Phase 1 clinical trial and (iv) $500,000 the earlier of May 2022 or approval of a NDA), an annual minimum royalty payment $20,000 and royalties (mid-range single digits) based on net sales on commercialized products covered by the patent-related rights set forth above.

As consideration for the rights granted under the second license agreement, UMI-176, Pelican is obligated to pay UM certain upfront license fees, and aggregate milestone payments of (i) $25,000 upon submission of an NDA, (ii) $25,000 upon approval of a NDA; (iii) $100,000 upon completion of Phase 1 clinical trial and (iv) $500,000 the earlier of May 31, 2024 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, UM 143 and UM 106, Pelican is obligated to pay UM certain upfront license fees, past and future patent costs, an annual minimum royalty payment $20,000 and royalties (mid-range single digits) based on net sales on commercialized products covered by the patent-related rights set forth above. The third license agreement with UM provides that in the event that Pelican terminates its second license agreement with UM, Pelican is obligated to pay UM an annual minimum royalty payment of $20,000 for each year after 2014 during the term of the third license agreement as well as the following milestone payments: (i) $25,000 upon submission of an IND; (ii) $25,000 upon approval of a NDA; (iii) $100,000 upon completion of a Phase 1 clinical trial; and (iv) $250,000 the earlier of May 31, 2024 or approval of a NDA. The royalty rates are subject to reduction if additional license rights from third parties are required to commercialize licensed products. In the event of a sublicense to a third party, Pelican is obligated to pay royalties to UM equal to a percentage of sublicense income. The third license agreement also provides that Pelican will not have to pay more than above royalty rates and sublicense fees if more than one license from UM is required to sell products covered by the licensed patent-related rights.

All of the above-described Pelican license agreements provide that the licensor has the right to terminate a subject license if the licensee (1) has not introduced, or at least used its best efforts to introduce, a licensed product in the commercial marketplace in the United States, European Union, or Japan by December 31, 2022 (December 2025 for the UMI-176 license agreement); (2) has not otherwise exercised diligence to bring licensed products to market; or (3) files, or has filed against it, a proceeding under the Bankruptcy Act, is adjudged insolvent, makes an assignment for the benefit of its creditors, or has an unreleased or unsatisfied writ of attachment or execution levied upon it. Upon an uncured material breach of an obligation under any one of the above license agreements by a party, the other party has the right to terminate that agreement upon 90 days' notice or 30 days' notice if the breach relates to payments due to UM. In the event of a termination, Pelican will be obligated to pay all amounts that accrued prior to such termination. Each of the above license agreements also contains other customary clauses and terms as are common in similar agreements between industry and academia, including the licensee's agreement to indemnify UM for liabilities arising out of the negligence of the licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

External Manufacturing

We have historically relied on third-party manufacturers to produce and store our product candidates for clinical use and currently do not operate our own manufacturing facilities. In order to promote efficiency and reduce our reliance on third-

party vendors, we plan to enhance our in-house development of bioanalytic, process development and manufacturing capabilities and offer such services to third parties for fees. We have entered into a lease for a 20,144 square foot facility in San Antonio, TX to conduct such services and are currently building the facility. Our proposed expansion in Texas is part of a company-wide-growth strategy to enhance efficiency and decrease our dependence on third-party vendors as we advance our clinical trials and general research and development. Operations at the facility are projected to commence by the second quarter of 2022, and we expect to fill production capacity by transitioning our outsourced manufacturing and development to in-house immediately, followed by contracting with external customers. However, there can be no assurance that we will be successful in these new operations. See the Key Capabilities section above for additional details.

The HS-110 product used in the inventor's Phase 1, and in our Phase 2 clinical trial was manufactured under cGMP (current good manufacturing practices). The gp96 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. Irradiation is a commonly used attenuation process that eliminates the ability of the gp96-Ig-containing cell lines to replicate but allows the cells to remain metabolically active and secrete gp96-Ig. The batches of frozen, irradiated drug product are stable for long periods of time and are thawed immediately prior to administration to patients.

The HS-130 product is being evaluated in a Phase I clinical trial for the treatment of select solid tumors. This product utilizes our *ComPACT*™ technology concept, which is designed to deliver the gp96 heat shock (HS-110) protein and a T-cell co-stimulatory fusion protein (OX40L) in HS-130. We have completed the cGMP manufacturing and nonclinical IND enabling activities to support the clinical development of this product.

PTX-35 is being evaluated in a Phase I clinical trial for the treatment of select solid tumors We have utilized an external vendor for the manufacture of PTX-35 and are planning the tech transfer of this asset to Scorpion for future biomanufacturing.

Anthim® (obiltoxaximab) is a best-in-class monoclonal antibody antitoxin for anthrax. Anthim received FDA approval and orphan drug exclusivity in 2016 for the treatment of inhalational anthrax, in combination with antibiotics, and as a prophylaxis when alternative therapies are not available or are not appropriate. Anthim was also approved in 2020 as the only licensed anthrax anti-toxin treatment in the EU, UK, and Canada. Anthim has previously been manufactured by an external vendor. We are in the process of completing the tech transfer of this asset to Scorpion for future biomanufacturing.

Competition

The pharmaceutical, biologics and the diagnostic industry is highly competitive and characterized by several established large companies, mid-sized companies, as well as smaller companies like ours. If our competitors' market products that are less expensive, safer, or more effective than any future products developed from our product candidates, or that reach the market before our approved product candidates, we may not achieve commercial success. Technological developments in our field of research and development occur at a rapid rate and we expect competition to intensify as advances in this field are made. We will be required to continue to devote substantial resources and efforts to our research and development activities. If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

Oncology

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. These companies might also succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products.

Our most significant oncology competitors, among others, are fully integrated pharmaceutical companies such as Eli Lilly and Company, Bristol-Myers Squibb Company, Merck & Co., Inc., Novartis AG, MedImmune, LLC (a wholly owned subsidiary of AstraZeneca plc), Johnson & Johnson, Pfizer Inc., MerckKGaA and Sanofi SA, and more established biotechnology companies such as Genentech, Inc. (a member of the Roche Group), Amgen Inc., Gilead Sciences, Inc. and its subsidiary Kite Pharma, Inc., and competing cancer immunotherapy companies such as, Bluebird Bio, Inc., Transgene SA, Agenus Inc., Advaxis, Inc., IMV Inc., Bavarian Nordic A/S, Celldex Therapeutics, Inc., and others.

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, and our competitors may develop and market products that are less expensive, more effective, or safer than our future products; commercialize competing products before we can launch any products developed from our product candidates; operate larger research and development programs, possess greater manufacturing capabilities or have substantially greater financial resources than we do; initiate or withstand substantial price competition more successfully than we can; have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent; more effectively negotiate third-party licenses and strategic relationships; and take advantage of acquisition or other opportunities more readily than we can.

The primary treatments for non-small cell lung cancer are surgery, radiation, chemotherapy, checkpoint inhibitors, targeted therapies and various combinations of each of these treatments. Many patients, particularly with advanced disease, are refractory to these treatments and are subsequently treated with several emerging biologic agents, including immunotherapy. Some examples of therapies commonly attempted with stage IIIB/IV NSCLC patients include: Opdivo® (nivolumab), Keytruda® (pembrolizumab), TECENTRIQ® (atezolizumab), LIBTAYO® (cemiplimab), Alimta® (pemetrexed), Avastin® (bevacizumab), Tarceva® (erlotinib), Gemzar® (gemcitabine), Paraplatin® (carboplatin), Taxol® (paclitaxel), Taxotere® (docetaxel), and Navelbine® (vinorelbine).

Despite the promise of checkpoint inhibitors (CPIs) such as pembrolizumab, there remains a significant unmet medical need as published studies demonstrate only a minority of single agent treated patients benefit with prolonged overall survival. Poor response to CPIs is thought to be partly attributable to properties of the tumor microenvironment and the concern that even if the “brake” set by immune checkpoints is released through CPI therapy, optimal antitumor immune responses may not be elicited due to a lack of antigen exposure. These observations have prompted the development of vaccines against cancer antigens that can generate high frequencies of tumor-specific T-cells. We believe the idea of dual immunotherapy with cancer vaccines and CPIs has garnered particular interest based on the hypothesis that the elevated frequencies of tumor-specific T-cells generated by cancer vaccines can be expanded and protected from attenuation through blockade of T-cell checkpoint receptors.

Our strategy is to emphasize what we believe to be our competitive advantages, which is that our products in development are expected to have less side effects than most other cancer therapies, the potential for enhanced overall survival in combination with approved therapies, may be available at lower prices than other therapies, and the potential to demonstrate efficacy in a number of oncology indications.

Biodefense

We anticipate our most significant competitor for Anthim® (obiltoxaximab) will be Emergent BioSolutions, Inc (Emergent). Emergent is the provider of the anthrax anti-toxin raxibacumab. Raxibacumab received FDA approval on December 14, 2012, while Anthim received FDA approval on March 18, 2016. Anthim and raxibacumab both inhibit the binding of anthrax toxin protective antigen (PA) to its cellular receptors, preventing the intracellular entry of the anthrax lethal factor and edema factor, the enzymatic toxin components responsible for the pathogenic effects of anthrax toxin. However, package inserts demonstrate that Anthim has a higher affinity equilibrium dissociation constant (Kd) at 0.33 compared to 2.78 nM of raxibacumab and a long-shelf life at 7 years for the final drug product. Anthim and raxibacumab have been supplied to the CDC’s strategic national stockpile. We anticipate based on previous delivery orders and option agreements that Anthim will continue to fulfill delivery orders as part of the Office of the Assistant Secretary for Preparedness & Response’s (ASPR) objective to diversify and acquire products with a longer shelf-life.

Internationally, Anthim was approved in 2020 as the only licensed anthrax antitoxin treatment in the European Union, United Kingdom, and Canada. In Canada, the approval of Anthim blocks future purchases of raxibacumab without Canadian Extraordinary-Use New Drug (EUND) approval. In the European Union, orphan drug exclusivity (10 year) at time of approval blocks competitors. We believe these approvals position Anthim well for increasing biosecurity preparedness in commercially approved ex-US ally territories and will be opportunistic in seeking strategic partnerships that maximize economic potential of this asset.

Contract Development Biomanufacturing Organization (CDMO)

We formed the subsidiary Scorpion Biological Services, Inc. to focus on developing bioanalytic, process development and biomanufacturing capability to support our biotherapeutics and discovery pipeline. We plan to offer excess biomanufacturing capacity to third parties as a fee-for-service CDMO model. Scorpion Biological Services is focused on cell- and gene-based therapies and large molecule biologics. We provide a broad array of biologics manufacturing, analytical and R&D services, offering services using American-made equipment, reagents, and materials. Scorpion couples cGMP biomanufacturing and quality control expertise with cutting edge capabilities in immunoassays, molecular assays, and bioanalytical methods to support the advancement of our development and commercial programs.

Considering our capabilities, we anticipate providing competition to established biomanufacturers including Lonza Group, Ltd and WuXi AppTec as well as recently announced biomanufacturing efforts from ThermoFisher Scientific, Inc. The COVID-19 pandemic revealed a critical shortage in US biomanufacturing capacity. Historically therapies could often take ~10 years to commercialize. However, with the implementation of the Emergency Use Authorization, complex, effective vaccines sped through pipelines at record speed and created new expectations for time to market, cost reduction, regulatory compliance, and good manufacturing performance. Considering the global cell and gene therapy clinical trials market size was valued at $9.2 billion in 2020 and is expected to expand at a compound annual growth rate (CAGR) of 22.3% from 2021 to 2028 per Grand View Research, we anticipate that a shortage of industry capacity may minimize the risk of direct competition.

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 and the manufacturer and/or sponsor under an approved new drug application are also subject to an annual program fee. These fees are typically increased annually.

The FDA undertakes to perform an initial filing review within 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Most such applications for standard review drug or biologic products are reviewed within ten to twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. The FDA can extend these reviews by three months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for products intended to treat a serious or life-

threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

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

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

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

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

Post-Approval Requirements

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

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain

state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

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

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Cell and Tissue-Based Biologics

Establishments that manufacture cell and tissue-based products must comply with the FDA's current good tissue practices, or cGTP, which are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of such products. The primary intent of the cGTP requirements is to ensure that T-cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also include requirements for a unified registration and listing system, donor screening and testing, adverse reaction reporting, and labeling.

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

Other U.S. Healthcare Laws and Compliance Requirements

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

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

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

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

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

under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

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

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

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

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

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to it, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to enter into government contracts, contractual damages,

reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Strict data privacy laws regulating the collection, transmission, storage and use of employee data and consumers' personally-identifying information are evolving in the European Union, U.S. and other jurisdictions in which we operate. Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the European Union, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR, together with national legislation, regulations and guidelines of the European Union member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E.U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins.

The GDPR also prohibits the transfer of personal data from the E.U. to countries outside of the E.U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e.g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E.U. personal data to the U.S.

Coverage, Pricing and Reimbursement

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

Different pricing and reimbursement schemes exist in other countries. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the

cost-effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

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

U.S. Healthcare Reform

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

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

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

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

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

Non-U.S. Regulation

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

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

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

Research and Development

We have built an internal and external research and development organization that includes expertise in discovery research, preclinical development, product formulation, analytical chemistry, manufacturing, clinical development and regulatory and quality assurance. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Our cancer trials have been registered on clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development. Research and development expenses were $18.8 million and $12.9 million during both years ended December 31, 2021 and 2020, 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 627 Davis Drive, Suite 400, Morrisville NC 27560. Our website address is www.heatbio.com. The information contained in, and that can be accessed through our website, is not incorporated into and is not a part of this report. We make available on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the U.S. Securities and Exchange Commission (the "SEC"). The following Corporate Governance documents are also posted on our website: Code of Business Conduct and Ethics and the Charters for the following Committees of the Board of Directors: Audit Committee, Compensation Committee, and Nominating Committee. Our phone number is (919) 240-7133 and our facsimile number is (919) 869-2128. Our filings may also be read and copied at the SEC's Public Reference Room at 100 F Street NE, Room 1580 Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov.

References to Heat Biologics also include references to our subsidiaries Pelican Therapeutics, Inc. ("Pelican"), 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., Skunkworx Bio, Inc. (formerly known as Delphi Therapeutics, Inc.), Scorpion Biological Services, Inc. (formerly Scorpion Biosciences, Inc), Blackhawk Bio, Inc., and Abacus Biotech, Inc., unless otherwise indicated. On May 30, 2012, we formed two wholly-owned subsidiaries, Heat Biologics III, Inc. and Heat Biologics IV, Inc. We formed Heat Biologics GmbH (Heat GmbH), a wholly-owned limited liability company, organized in Germany on September 11, 2012 and Heat Biologics Australia Pty LTD, a wholly-owned company, registered in Australia on March 14, 2014. On October 25, 2016, we formed a wholly-owned subsidiary, Zolovax, Inc., to focus on the development of gp96 based vaccines targeting Zika, HIV, West Nile, dengue, yellow fever, and SARS-CoV-2. In June 2012, we divested our 92.5% interest in Pelican (formerly known as Heat Biologics II, Inc.). On April 28, 2017, we completed the acquisition of an 80% controlling interest in Pelican, a related party prior to acquisition. In October 2018, we entered into an agreement with UM whereby UM exchanged its shares of stock in Heat's subsidiaries, Heat I, Inc. and Pelican, resulting in us owning 100% of Heat I, Inc. and increasing our controlling ownership in Pelican from 80% to 85%. We assigned our proprietary rights related to the development and application of our ImPACT® therapy platform to Heat Biologics I, Inc. In November 2018, we formed Skunkworx Bio, Inc. (formerly known as Delphi Therapeutics, Inc.) which uses a unique and proprietary platform to generate new biological entities that we may rapidly advance into clinical development. Also, in November 2018, we formed Scorpion Biological Services, Inc. ("Scorpion") (formerly known as Scorpion Biosciences, Inc.), to focus on developing bioanalytic, process development and manufacturing capability to service our in-house requirements as well as potentially those of others. In February 2021, we formed Abacus Biotech, Inc., a wholly-owned subsidiary to pursue additional opportunities related to our business.

We are also a "smaller reporting company", as defined in Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited

financial statements. We will cease to be a smaller reporting company if we have (i) more than $250 million in market value of our shares held by non-affiliates as of the last business day of our most recently completed second fiscal quarter or (ii) more than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates more than $700 million as of the last business day of our second fiscal quarter.

On December 11, 2020, we effected a one-for-seven- reverse stock split. All per share numbers reflect the one-for seven reverse stock split.

Human Capital

We believe that our success depends upon our ability to attract, develop, retain and motivate key personnel. Our management and scientific teams possess considerable experience in drug discovery, research and development, manufacturing, clinical and regulatory affairs and believe we directly benefit from this experience and industry knowledge. Our research team comprises B.S., M.S. and Ph.D.-level scientists with expertise in oncology, immunology, and molecular biology.

As of December 31, 2021, we had a total of 49 full-time employees, of which 14 are part of our research team located in San Antonio, Texas, 16 are part of our research team located in Morrisville, North Carolina, 4 are part of our research team located in New Brunswick, New Jersey and 15 are part of our corporate team. We anticipate increasing our headcount upon the consummation of the pending acquisition of Elusys. We consider our relationships with our employees to be good. 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.

We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We consider our relations with our employees to be good. Although, management continually seeks to add additional talent to its work force, management believes that it has sufficient human capital to operate its business successfully.

Our compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance. Specifically:

- we provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location;
- we engage nationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our executive compensation and benefit programs and to provide benchmarking against our peers within the industry;
- we align our executives' long-term equity compensation with our shareholders' interests by linking realizable pay with stock performance;
- annual increases and incentive compensation are based on merit, which is communicated to employees at the time of hiring and documented through our talent management process as part of our annual review procedures and upon internal transfer and/or promotion; and
- all employees are eligible for health insurance, paid and unpaid leaves, a 401K retirement plan with employer matching contributions (maximum of 4% match) and life and disability/accident coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs, including flexible time-off, telemedicine, and paid parental leave.

Health and Safety

The health and safety of our employees is our highest priority, and this is consistent with our operating philosophy. Accordingly, with the global spread of the ongoing novel coronavirus pandemic, we have implemented plans designed to address and mitigate the impact of the COVID-19 pandemic on the safety of our employees and our business, which include:

- adding work from home flexibility;
- adjusting attendance policies to encourage those who are sick to stay home;
- increasing cleaning protocols across all locations; and
- initiating regular communication regarding impacts of the COVID-19 pandemic, including health and safety protocols and procedures.

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 a result of different factors, including the risks we face described below.

Risks Relating to our Company, Financial Position and Capital Requirements

We have had limited operations to date.

To date, we have not generated any revenue from product sales and substantially all of our revenue to date has been grant revenue that Pelican has received from CPRIT and a small amount of revenue from a research funding agreement. We do not anticipate generating any revenue from product sales for several years as to date we do not currently have any products approved for commercial sale. Although we will acquire inventory of Anthim, upon the consummation of the pending acquisition of Elusys, we will not acquire a significant amount of inventory for sale and therefore it will require several years for us to manufacture additional quantity of Anthim and receive any regulatory approvals. Therefore, we do not anticipate generating significant revenue from Anthim sales for several years and in fact anticipate to incur additional expenses associated with such product before generating significant revenue from sales of Anthim. Even if we generate revenue from product sales, which is not anticipated for several years, if at all, there can be no assurance that we will be profitable. In addition, we are entering into a new line of business, the provision of contract development and manufacturing services and no assurance can be given that we will be able to generate revenue as a contract development and manufacturing organization ("CDMO") or that we will be able to consummate our business strategy and plans. Financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. The building of the manufacturing facility will require us to incur significant expenses before we realize any revenue from such facility. 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

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. To date, we have not obtained approval for commercialization of any of the products we have

developed and have not proven that we can successfully commercialize any product. In addition, we have never provided manufacturing services as a contract development and manufacturing organization and we have no proven that we can successfully operate a CDMO facility. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

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

While various members of our management and staff have prior significant experience in conducting cancer trials, our company, to date, has not successfully completed any pivotal clinical trials and we have limited experience conducting and enrolling patients in clinical trials. Until the last few years, our operations, including the operations and those of our subsidiaries, have been limited primarily to organizing and staffing, acquiring, developing and securing our proprietary technology and undertaking preclinical trials and preparing for and conducting our Phase 1 and Phase 2 clinical and preclinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We have a limited operating history conducting commercial development of bioanalytics, process development and manufacturing activities, which may limit the ability of investors to make an informed investment decision.

We plan to expand our operations by operating a facility for the development of bioanalytics, process development and manufacturing activities. To date, we have limited experience manufacturing products for third parties and ourselves. Because of the numerous risks and uncertainties associated with development and manufacturing, we are unable to predict if we will be successful in providing such services to ourselves or third parties. Although we plan to use our anticipated facility to service our internal manufacturing needs, we also intend to generate revenue to offset the expenses we incur in operating the facility as well as the initial start-up expenses from third parties. Our ability to generate this revenue will depend, in part, on our ability to attract and maintain customers for our development, manufacturing and technology transfer services and on the amount of spent by the customers on such services. If our anticipated facility fails to attract customers and operate at sufficient capacity, our margins will suffer, and we may not be able to fund the costs we incur to operate the facility. Our bioanalytics, process development and manufacturing activities will also depend, in part, on our ability to attract and retain an appropriately skilled and sufficient workforce to operate our development and manufacturing facility and our ability to comply with various quality standards and environmental, health and safety laws and regulations.

We have incurred net losses every year since our inception and expect to continue to incur increased expenses and generate operating losses and experience negative cash flows and it is uncertain whether we will achieve profitability.

For the years ended December 31, 2021 and 2020, we incurred a net loss of $35.4 million and $26.4 million, respectively. We have an accumulated deficit of $165.7 million through December 31, 2021. 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. As stated above, we do not anticipate generating significant revenue from sales of our products for several years or from our manufacturing facility until such time as it is fully operational. 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 that are under development will be approved for commercial sale, or even product candidates and products that are approved for commercial sale we will ever generate significant sales or achieve profitability. Furthermore, there can be no assurance that we generate sufficient revenue from manufacturing services to support the expenses anticipated to be incurred by the manufacturing facility. 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, consummate the pending acquisition of Elusys and are successful in launching Anthim or are successful in generating revenue as a CDMO, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue

to incur significant operating expenses and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical development and conduct clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure;
- devote resources to constructing a facility for the development of bioanalytics, process development and manufacturing activities;
- launch Anthim and engage in commercial scale manufacturing of Anthim, upon consummation of the pending acquisition of Elusys; 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 support our long-term business plans 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, 2021, our operating activities used net cash of approximately $38.1 million and as of December 31, 2021, our cash and cash equivalents and short-term investments were approximately $96.4 million. During the year ended December 31, 2020, our operating activities used net cash of approximately $22.0 million and as of December 31, 2020 our cash and cash equivalents and short-term investments were approximately $111.8 million. We have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, 2021, our accumulated deficit totaled $165.7 million and as of December 31, 2020, our accumulated deficit totaled $130.6 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. We do not expect to derive revenue from any of our product candidates currently in development in the near future until we or our potential partners successfully commercialize our products and in order to generate significant revenue from Anthim sales we will need to engage in full scale manufacturing of Anthim which will take several years. 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 and if and when we consummate the pending acquisition of Elusys and commence full scale manufacturing of Anthim. 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. In addition, we expect our expenses to increase due to the build out of the manufacturing facility in San Antonio and the purchase of equipment for the facility.

We will need to raise additional capital to fund our long term operations and milestone payments and we cannot be certain that funding will be available to us on acceptable terms on a timely basis, or at all. To meet our financing needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which we expect will include sales of common stock through at the market issuances, debt financings and/or funding from partnerships or collaborations. Our ability to raise capital through the sale of securities may be limited by our number of authorized shares of common stock and various rules of the SEC and the NYSE American that place limits on the number and dollar amount of securities that we may sell. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders, assuming we are able to sufficiently increase our authorized number of shares of common stock. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. If we fail to raise additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities or continue to maintain our listing on the NYSE American. 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 do not anticipate generating revenue from our product sales for many years and we do not anticipate generating revenue from manufacturing services for at least one year, when the facility is operational.

We currently do not have regulatory approvals for the sale of any products that we have been developing and we do not expect to derive significant revenue from the sale of Anthim upon consummation of the pending acquisition of Elusys until we can manufacture a sufficient quantity of Anthim which we expect will take several years after the acquisition of Elusys is consummated to obtain the necessary approvals and secure a manufacturing slot. Although the Merger Agreement provides that we will acquire some inventory of Anthim, the inventory acquired will not be a significant amount and is not expected to generate significant revenue. In addition, until our manufacturing facility that we are building is fully operational, we do not expect to generate significant revenue from services and expect to incur significant expenses for the next several years.

Business Disruptions could seriously harm our business, financial condition, and results of operations.

Our operations, and those of our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), geopolitical events, including civil or political unrest (such as the ongoing conflict between Ukraine and Russia), terrorism, insurrection or war, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

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

Since December 2019, a novel strain of coronavirus, COVID-19, has spread to multiple countries, including the United States where we have planned or active clinical trial sites. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic. In response to the COVID-19 pandemic, many state, local, and foreign governments have put in place, and others in the future may put in place, quarantines, executive orders, shelter-in-place orders, and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions, or the perception that such orders or restrictions could occur, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions, and cancellation or postponement of events, among other effects that could negatively impact productivity and disrupt our operations.

As the COVID-19 pandemic continues to spread around the globe, we could experience disruptions that could severely impact our business and clinical trials, including:

- delays in initiation of or difficulties in enrolling patients in our clinical trials due to a lack of personal protection equipment supply for patients and subsequent temporary cessation of non-essential patient procedures;

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

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

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

The global outbreak of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 outbreak may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. We do not yet know the full extent of potential delays or impacts on our business, operations, or the global economy as a whole. While the spread of COVID-19 may eventually be contained or mitigated, there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, or that the global economy will recover, either of which could seriously harm our business.

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

None of the product candidates for which we have conducted clinical trials are currently approved for sale and we cannot guarantee that they will ever have any drug products approved for sale. The Anthim product that we intend to acquire upon consummation of the Merger, although approved for commercial sale, will not be manufactured at the facility that manufactured the Anthim previously sold by Elusys and therefore the facility will require regulatory approval. 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. 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 NYSE American that place limits on the number of shares of stock that may be sold. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

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

To date, 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, HS-130 and PTX-35 are our only current products in clinical trials. Our other product candidates are all at a pre-clinical stage. We expect that at least one Phase 3 clinical trial of HS-110 will be required to gain approval by the FDA. Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval, and commercialize our product candidates, which may never occur. Before commercializing any 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.

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

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. On February 9, 2021, the reported low sale price of our common stock was $11.51 per share and the reported high sales price was $17.00 per share. For comparison purposes, on December 31, 2021, the price of our common stock closed at $3.04 per share. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance or prospects. In addition, the recent outbreak of the novel strain of coronavirus (COVID-19) has caused broad stock market and industry fluctuations. The stock market generally and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- investor reaction to our business strategy;
- the success of competitive products or technologies;
- our continued compliance with the listing standards of the NYSE American;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- results of our clinical trials;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;

- developments concerning our collaborations or partners;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability to consummate the acquisition of Elusys and generate revenue from Anthim sales;
- our ability to generate revenue from our CDMO facility;
- our ability or inability to raise additional capital and the terms on which we raise it;
- declines in the market prices of stocks generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- other events or factors, including those resulting from suchevents, or the prospect of such events, including war, terrorism and other international conflicts, such as the recent Russian invasion of Ukraine as well as continued and nay new sanctions against Russia by, among others, the European Union and the Unites States, which restrict a wide range of trade and financial dealings with Russia and Russia parties, public health issues including health epidemics or pandemics, such as the recent outbreak of the novel coronavirus (COVID-19), and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. There can be no guarantee that our stock price will remain at current prices or that future sales of our common stock will not be at prices lower than those sold to investors.

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

We regularly review acquired intangible assets for impairment when events or changes in circumstances indicate that the carrying value may not be recoverable. We test goodwill and indefinite-lived intangible assets for impairment at least annually. Factors that may be considered a change in circumstances, indicating that the carrying value of the intangible assets may not be recoverable, include: macroeconomic conditions, such as deterioration in general economic conditions; industry and market considerations, such as deterioration in the environment in which we operate; cost factors, such as increases in labor or other costs that have a negative effect on earnings and cash flows; our financial performance, such as negative or declining cash flows or a decline in actual or planned revenue or earnings compared with actual and projected results of relevant prior periods; other relevant entity-specific events, such as changes in management, key personnel, strategy, or customers; and sustained decreases in share price. During the year ended December 31, 2021, we recorded a non-cash goodwill impairment charge and indefinite-lived intangible assets impairment charge totaling $3.8 million.

Risks Related to Our Clinical Development, Regulatory Approval and Commercialization

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

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

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

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

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

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

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

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

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

Because our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. HS-110, HS-130 and PTX-35 are our only current product candidates in clinical trials and our other product candidates are all in the preclinical stage of development. Although we have completed enrollment for a Phase 2 clinical trial for HS-110 and a Phase 1 clinical trial of HS-130, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review.

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

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

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

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

- imposition of clinical hold or suspension of our clinical trials by regulatory authorities; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend or terminate our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our 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 T-cell line could be materially and adversely affected. Although we have implemented certain additional procedures to properly identify our cell lines, we may not be able to detect that a cell line has been mischaracterized or mislabeled by a third party.

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

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

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

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

We currently rely upon our gp96 platform for development of many of our product candidates, which if unsuccessful may impact the success of several of our product candidates.

We are currently developing two product candidates HS-110 and HS-130 based upon our gp96 platform. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our gp96 platform. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of our gp96 platform, which may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of product candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market any product in the United States unless and until we receive approval of a BLA, from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in such countries. We have never submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of its product for many reasons.

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 oncology competitors have oncology compounds already approved or in development and there are currently a few approved COVID-19 vaccines and one other approved Anthrax therapeutic. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

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

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

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

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

We have developed certain expertise in the formulation, development and/or manufacturing of biologics; however to date we have relied on third parties for substantially all of our manufacturing needs. 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 currently lack all of the necessary resources and expertise to formulate or manufacture our own product candidates. The investigational products for our clinical trials are manufactured by our contractors under current good manufacturing practices, ("cGMPs") and we have entered into agreements with commercial-scale manufacturers for the production and supply of investigational product for additional Phase 2 and Phase 3 clinical trials as well as commercialization. Our agreement with the manufacturer of our HS-110 product expired in October 2019. In addition, the manufacturer of our HS-110 has closed its facility where it manufactured our HS-110 and therefore future manufacture of HS-110 by such manufacturer will require additional regulatory approvals for the new manufacturing site. Any future orders with such manufacturer for HS-110 will be pursuant to the terms of purchase orders unless a new definitive agreement is entered into. If not renegotiated, we may experience longer manufacturing lead times for any purchase orders we place with either such manufacturer under purchase orders or any new manufacturer, especially in light of additional regulatory requirements due to the change in the manufacturing facility. In addition, our manufacturer for many of our other product candidates, do not currently have the capacity to engage in large scale manufacturing of our products and therefore we will be required to engage new manufacturers for many of our current early stage product candidates. 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. We have performed assay development work at our Texas laboratory to support our clinical needs as well as those of third parties. Elusys's agreement with the manufacturer of Anthim is an exclusive agreement that expires ten years after regulatory approval of Anthim at a 6,000 liter scale for the manufacture of Anthim at a new facility at a higher scale. To date, the manufacturer has only manufactured Anthim at a 5,000 liter scale. Therefore, future manufacture of Anthim by such manufacturer will require additional regulatory approvals for the new manufacturing site and new scale. In an effort to decrease our dependence upon third party manufacturers and enhance efficiency, we are exploring the establishment of process development and manufacturing capability to support our clinical trials and potentially third party manufacturing needs. If any of our current product candidates, or any product candidates we may develop or acquire in the future, receive FDA approval, we may rely on one or more third-party contractors for manufacturing. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to renew or renegotiate current agreements on favorable terms or identify manufacturers on acceptable terms or at all because the number of potential manufacturers with appropriate expertise and facilities is limited.

- If we change manufacturers at any point during the development process or after approval, which for several of our product candidates we expect to be required to do for later stage clinical trials and commercialization, 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 our other product candidates produced by the two different manufacturers at some point during the clinical development process.

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

- Our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and with the quality required to meet our clinical needs and commercial needs, if any.

- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, and corresponding state agencies to ensure compliance with cGMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

- Our contract manufacturers have in the past and may in the future encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. Our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to assess compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we or our contract manufacturers are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

- If we establish in-house development and manufacturing capabilities, there are a number of risks that could impact our financial condition, operating results and cash flows due to disruption of operations at the location or facility which may impede our ability to deliver assays or manufacture our products.

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.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We also rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that it develops would be harmed, its costs could increase, and our ability to generate revenues could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

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. We currently depend on third-party suppliers for key materials and services used in its research and development, as well as manufacturing processes, and are subject to certain risks related to the loss of these third-party suppliers or their inability to supply us with adequate materials and services. We do not control the manufacturing processes of the CDMOs, with whom it contracts and is dependent on these third parties for the production of its therapeutic candidates in accordance with relevant regulations (such as current Good Manufacturing Practices, or "cGMP", which includes, among other things, quality control, quality assurance and the maintenance of records and documentation.

To succeed, clinical trials require adequate supplies of study material, which may be difficult or uneconomical to procure or manufacture and there can be no assurance that we will successfully procure such study material or even if procured, that we can do so in quantities and in a timely manner to allow our clinical trials to proceed as planned. We and our suppliers and vendors may not be able to (i) produce our study material to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us, or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or manufacturer which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. Although we believe additional manufacturers and vendors are available, if any of our manufacturers or vendors were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to satisfy the supply commitments, the process of locating and qualifying alternate sources could require up to several months, during which time our production could be delayed. Any such curtailment in the availability of products could have a material adverse effect on our business, financial position and results of operations. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs. Although we do believe that replacement manufacturers and vendors are available, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities. If we are unable to establish in-house development and manufacturing capabilities, we may not be able to reduce our dependency on third-party manufacturers.

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

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

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

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

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

If the FDA approves any of our product candidates, the labeling, manufacturing, packaging, adverse event reporting, storage, advertising, promotion and record keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. As stated above, our manufacture of Anthim upon consummation of the pending acquisition of Elusys will require additional regulatory approval. 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

To date, we have not had any sales, marketing or distribution capabilities. Although we intend to hire some of the Elusys employees who have such experience, we do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our other 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 Anthim and the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Among policy makers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, The Patient Protection and Affordable Care Act (ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to

individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

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

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

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

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

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

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

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

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

or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

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

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

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our product candidates in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- limits on our ability to penetrate international markets if our product candidates cannot be processed by a manufacturer appropriately qualified in such markets;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales and distributors' activities.

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

We may acquire other businesses or form joint ventures or make investments in other companies or technologies or new lines of business 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 may also make investments in other companies of technologies, new lines of business, or expansion of research bioanalytical development and manufacturing capacities. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. Other than our acquisition of the equity of Pelican in 2017 and planned acquisition of Elusys, 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 or investments in other companies or technologies or

new lines of business 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.

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

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

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

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

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

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

We rely extensively on our information technology systems and are vulnerable to damage and interruption.

We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. Likewise, data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. A cyber-attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation.

Any failure to maintain the security of information relating to our customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

In connection with the sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. In addition, as the manufacturer of biodefense product sold to the U.S. government, Elusys has access to highly confidential government information. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

We may face particular data protection, data security and privacy risks in connection with the European Union's Global Data Protection Regulation and other privacy regulations.

Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. If we should engage in business in the European Union, including selling products such as Anthim, upon consummation of the acquisition of Elusys, we will be subject to such laws. For example, in the European Union, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR, together with national legislation, regulations and guidelines of the European Union member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR,

including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E.U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins.

The GDPR also prohibits the transfer of personal data from the E.U. to countries outside of the E.U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e.g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E.U. personal data to the U.S.

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 potential international expansion, including sales of Anthim, upon consummation of the pending acquisition of Elusys, outside of the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax and transfer pricing laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- being subject to additional privacy and cybersecurity laws;
- failure by us or distributors to obtain regulatory approvals for the sale or use of products in various countries;
- difficulties in managing foreign operations;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales and distributors' activities.

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

Our operating results may be adversely affected by fluctuations in foreign currency exchange rates and restrictions on the deployment of cash across global operations.

Although we report operating results in U.S. dollars, if we engage in sales of products internationally, our revenues and expenses are or will be denominated in currencies other than the U.S. dollar, particularly in Europe. Fluctuations in foreign currency exchange rates can have a number of adverse effects on us. Because our consolidated financial statements are presented in U.S. dollars, we will be required to translate revenues, expenses and income, as well as assets and liabilities, into U.S. dollars at exchange rates in effect during or at the end of each reporting period. Therefore, changes in the value of the U.S. dollar against other currencies will affect revenues, income from operations, other income (expense), net and the value of balance sheet items originally denominated in other currencies. There is no guarantee that our financial results will not be adversely affected by currency exchange rate fluctuations. In addition, in some countries we could be subject

to strict restrictions on the movement of cash and the exchange of foreign currencies, which could limit our ability to use these funds across its global operations.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and other worldwide anti-bribery laws.

The FCPA and anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business or other commercial advantage. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties, including criminal and civil fines, potential loss of export licenses, possible suspension of the ability to do business with the federal government, denial of government reimbursement for products and exclusion from participation in government health care programs. We may operate in jurisdictions that have experienced governmental and private sector corruption to some degree, and, in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. We cannot assure that the internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by affiliates, employees or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations.

Risk Related to the Pending Merger and Elusys.

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

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

- the respective representations and warranties of us and Elusys shall be true and correct in all material respects as of the date of the Merger Agreement and the closing;
- performance or compliance in all material respects by us and Elusys with their respective covenants and obligations in the Merger Agreement;
- Elusys shall have obtained any consents and waivers of approvals required in connection with the Merger; and
- no material adverse effect with respect to us or Elusys or its subsidiaries shall have occurred since the date of the Merger Agreement.

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

The Merger is expected to provide certain strategic benefits to both parties that would not be realized if Elusys was not acquired by Heat. Specifically, we believe the Merger should provide certain strategic benefits which would enable us to accelerate our business plan to combat infectious disease. The market price of our common stock however may decline as a result of the Merger if the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by us or Elusys or investors, financial analysts, or industry analysts. There can be no assurance that these anticipated benefits of the Merger will materialize or that if they materialize will result in increased stockholder value or revenue stream to the combined company.

Our Chief Executive Officer and Chairman of the Board of Directors has a conflict of interest that may influence him to support funding of Elusys.

Jeffrey Wolf, the Chief Executive Officer and Chairman of the Board of Directors is the founder of Elusys, served on its Board of Directors, and received a financial interest in the surviving subsidiary. Mr. Wolf has a direct or indirect financial interest in both Elusys and our company.

We may be unable to successfully integrate the Elusys businesses with our current management and structure.

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

- assimilating Elusys's technology and retaining personnel;
- estimating the capital, personnel and equipment required for Elusys based on the historical experience of management with the businesses they are familiar with; and
- minimizing potential adverse effects on existing business relationships.

Elusys is substantially dependent on various US Government contracts that are material to its business and if the agreements were to be terminated, it would have an immediate material adverse effect on its business, operating results and financial condition.

Elusys expects to receive approximately $80 million in the aggregate from the SNS upon fulfillment of existing U.S. Government contracts CLIN 0001-0007 for ANTHIM, all of which subject to adjustments is to be paid over to the shareholders of Elusys. Elusys also intends to continue to seek other U.S. Government contracts for Anthim. If Elusys breaches the terms of its U.S. Government contracts, the U.S. Government has the right to terminate the agreement. If Elusys were to lose or otherwise be unable to maintain these contracts or be unable to secure new U.S. Government contracts in the future for Anthim, it would have an immediate material adverse effect on its business, operating results and financial condition.

Even if the Merger is consummated, we do not anticipate generating revenue from Anthim sales for several years.

Even if the Merger is consummated, we do not expect to derive revenue from the sale of Anthim for several years. Although after the consummation of the Merger, we will receive payments from orders for Anthim previously contracted for prior to Closing, we will not retain such payments and instead will redistribute such payments to the stockholders of Elusys, subject to adjustments. Since substantially all of the current Anthim inventory is earmarked for contracts that have been previously entered into, we will be required to manufacture a new batch of Anthim before any new contracts for sales of Anthim can be fulfilled. Since it is not anticipated that we will have regulatory approvals or be able to complete manufacturing of Anthim for several years, it is not anticipated that we will generate revenue from Anthim sales for many years and there can be no assurance that regulatory approvals will be received or if received that they will be received when anticipated.

Our ability to generate product revenues from sale of Anthim after consummation of the Merger is dependent upon government spending and compliance with the government contracts.

To date, all of Elusys' revenue has been derived from sale of Anthim to U.S. Governmental agencies. If the U.S. government were to cut its healthcare spending and in particular its biodefense spending, our ability to generate revenue after consummation of the Merger from Anthim sales will be adversely impacted.

To date, Anthim has been sold to a limited number of customers and there can be no assurance that after consummation of the Merger we will be successful in expanding the number of Anthim customers.

To date, all of the sales of Anthim have been a limited number of sales to agencies of the United States. Our strategy is to expand the number of sales to such agencies as well as expand the customer base outside of the United States. To date, we have not had any experience with distribution and sales of commercial products. There can be no assurance that there will be additional demand for Anthim or that we will be successful in our distribution and sale efforts.

In order to develop Anthim, wet will have to devote significant resources to Anthim.

Pursuant to the terms of the Merger Agreement, we have agreed to use reasonable efforts to commercialize Anthim. Obtaining requisite regulatory approvals for the manufacture and sale of Anthim and manufacturing costs are anticipated to be significant. We have incurred significant losses from operations to date and expect our expenses to increase in connection with our ongoing activities, and the addition of Elusys' activities. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all.

Elusys has been manufacturing the drug product with one manufacturer pursuant to the terms of an exclusive manufacturing agreement

To date, all Anthim bulk drug substance has been manufactured by a one manufacturer at a 5,000 liter scale pursuant to the terms of an exclusive manufacturing agreement. Elusys' ability to manufacture additional batches of bulk drug substance will be dependent upon the slotting availability of the manufacturer. In addition, the manufacturer has decommissioned its 5,000 liter assets and therefore any further manufacturing by the manufacturer will be at a 6,000 liter scale. This new scale will require new regulatory approval from the FDA, the timing of approval, if obtained cannot be certain. In addition, there is no assurance that the bulk drug substance can be successfully manufactured at a 6,000 liter scale in a cost efficient manner.

Risks Related to Intellectual Property

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

We intend to rely on a combination of common law copyright, patent, trademark, and trade secret laws and measures to protect our proprietary information. We have obtained exclusive rights to license the technology for which patent protection has been obtained; however, certain patents expired in 2019 and such protection does not prevent unauthorized use of such technology. In addition, our licenses 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.

Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture market share. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. As a result, in response to the COVID-19 pandemic, it is possible that certain countries may take steps to facilitate compulsory licenses that permit the distribution of a COVID-19 vaccine in those countries. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the relevant patent rights. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, competitors may design around our technology or develop competing technologies.

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

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

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing drug or therapy candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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

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

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

For the years ended December 31, 2022, and 2023 our minimum annual payment obligations under our licensing agreements required to be paid by us or our subsidiaries with the passage of time, are approximately $0.8 million and $0.07 million, respectively. No assurance can be given that we will generate sufficient revenue or raise additional financing to make these minimum royalty payments or milestone payments owed to the Pelican Stockholders pursuant to the terms of the stock purchase agreement that we entered into with Pelican and certain stockholders of Pelican in March 2017. The license agreements also provide for certain developmental milestones, as does the purchase agreement that we entered into

with Pelican and certain stockholders of Pelican in March 2017, including future payments to Pelican based on the achievement of certain milestones. No assurance can be given that we will meet all of the required developmental milestones or have sufficient funds to make required payments under the purchase agreement. Any failure to make the payments or reach the milestones required by the license agreements would permit the licensor to terminate the license and any failure to make payments under the purchase agreement would constitute a default under the purchase agreement. If we were to lose or otherwise be unable to maintain these licenses, it would halt our ability to market our products and technology, which would have an immediate material adverse effect on our business, operating results and financial condition.

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.

General Risk Factors

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

We are highly dependent on our principal scientific, regulatory and medical advisors and our chief executive officer. Other than a $2.0 million insurance policy we hold on the life of Jeffrey Wolf, we do not have "key person" life insurance policies for any of our officers or advisors. The loss of the technical knowledge, management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

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

We will need to hire additional qualified personnel with expertise in preclinical and clinical research, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. Over the next 12 months, we expect to hire additional new employees both in North Carolina and for Scorpion in Texas. In fact, due to the CPRIT Grant and tax incentives in Texas, we are required to hire and maintain employees in Texas. We compete for qualified individuals with numerous biopharmaceutical companies, universities, and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful especially in light of the CPRIT Grant requirements, including the requirement that Pelican maintain its headquarters in Texas and use certain vendors, consultants and employees located in Texas. Attracting and retaining qualified personnel will be critical to our success.

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

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

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

Our failure to meet the continued listing requirements of The NYSE American LLC (the "NYSE American") could result in a de-listing of our common stock.

Our shares of common stock are currently listed on the NYSE American. If we fail to satisfy the continued listing requirements of the NYSE American, such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder's equity requirement, NYSE American may take steps to de-list our common stock. Any de-listing would likely have a negative effect on the price of our common stock and would impair stockholders' ability to sell or purchase their common stock when they wish to do so. In the past our common stock was listed on the Nasdaq Capital Market and we received notices from the Listing Qualifications Department of Nasdaq Stock Market LLC ("Nasdaq") that we failed to comply with the stockholder's equity requirements and the minimum closing bid requirements. On June 21, 2019, we received written notice from the Listing Qualifications Department of the Nasdaq Stock Market LLC notifying us that for the preceding 30 consecutive business days (May 9, 2019 through June 20, 2019), our common stock did not maintain a minimum closing bid price of $1.00 per share ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). On July 24, 2020, we received written notice from The Nasdaq Capital Market that from July 10, 2020 through July 23, 2020, the closing bid price of our common stock has been at $1.00 per share or greater and accordingly we had regained compliance with Nasdaq Listing Rule 5550(a)(2) and the matter was now closed. There can be no assurance given that we will be able to continue to satisfy our continued listing requirements and maintain the listing of our common stock on the NYSE American going forward.

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

As of March 9, 2022, awards for 2,925,664 shares of common stock are outstanding under our equity compensation plans and 423,225 shares of common stock remain available for grants under the plans. In addition, as of March 9, 2022, we have warrants exercisable for 747,383 shares of our common stock to third parties in connection with our public offerings. To the extent that outstanding stock options and warrants are exercised, or additional securities are issued, dilution to the interests of our stockholders may occur. Moreover, the terms upon which we will be able to obtain additional equity capital may be adversely affected since the holders of the outstanding options can be expected to exercise them at a time when we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than those provided in such outstanding options.

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

Our certificate of incorporation authorizes the issuance of 250,000,000 shares of our common stock and 10,000,000 shares of preferred stock. In certain circumstances, the common stock, as well as the awards available for issuance under the incentive plans, can be issued by our Board of Directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership of us held by holders of preferred stock and common stock. Our Board of Directors is authorized to create and issue from time to time, only with stockholder approval, up to an aggregate of

10,000,000 shares of preferred stock of which 8,212,500 have been designated. The authority to designate preferred stock may be used to issue series of preferred stock, or rights to acquire preferred stock, that could dilute the interest of, or impair the voting power of, holders of the common stock or could also be used as a method of determining, delaying or preventing a change of control.

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

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

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

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain types of state actions that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

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

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, employees, control persons, underwriters, or agents, which may discourage lawsuits against us and our directors, employees, control persons, underwriters, or agents. Additionally, a court could determine that the exclusive forum provision is unenforceable, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find these provisions of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, or results of operations.

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

On March 9, 2022, we had 25,649,824 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.

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 $11.55, $11.09 and $5.78 per share. In the event that our common stock price does not exceed the exercise price of our previously issued warrants during the period when the warrants are exercisable, the warrants may not have any value.

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

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

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

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

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

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

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

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

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

None.

Item 2. ***Properties***

Facilities

Our executive offices are located at 627 Davis Drive, Suite 400, Morrisville, North Carolina 27560. In October 2019, we entered into a lease that expires October 31, 2027 for 7,492 square feet of office and laboratory space for monthly rent of $17,525 exclusive of payments required for maintenance of common areas and utilities. In June 2021, we entered into a lease that expires 96 months from rent commencement date for 15,996 square feet of expanded office and laboratory space for monthly rent of $43,656 exclusive of payments required for maintenance of common areas and utilities. On the day immediately preceding the rent commencement date, the current lease will terminate.

In January 2018, Pelican entered into a five-year lease for 5,156 square feet of office and laboratory space located in San Antonio, Texas for monthly rent of $9,668, exclusive of payments required for maintenance of common areas and utilities.

In July 2020, and amended August 2021, we entered into a lease for our Skunkworx subsidiary in North Brunswick, New Jersey that is expected to expire July 1, 2023 for 2,725 square feet of laboratory space for monthly rent of $7,232 exclusive of payments required for utilities.

On October 5, 2021, Scorpion entered into a lease for approximately 20,144 square feet of office and lab space located at 1305 E. Houston Street, San Antonio, Texas 78205 for general office, laboratory, research, analytical, and/or biomanufacturing purposes for monthly base rent starting at $50,360.00 and increasing at the rate of three percent (3%) on an annual basis up to a maximum monthly base rent of $76,174.02.

We believe our existing properties are adequate for our current needs.

Item 3. ***Legal Proceedings***

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

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

Not applicable.

PART II

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

Market Information

Since February 14, 2022, our common stock has traded on the NYSE American under the symbol "HTBX". Prior to February 14, 2022, our common stock traded on the Nasdaq Capital Market under the symbol "HTBX".

Holders

As of March 9, 2022, there were approximately 21 stockholders of record of our common stock. The number of holders of record is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

On December 10, 2020, we announced a reverse stock split of our shares of common stock at a ratio of one-for-seven. The reverse stock split took effect at 12:01 a.m. ET on December 11, 2020, and our common stock began to trade on a post-split basis at the market open on December 11, 2020. During our annual stockholders meeting held February 27, 2020, 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 seven 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 on the effective date of the reverse split from approximately 159.8 million shares to approximately 22.8 million. It also subsequently adjusted outstanding options issued under our equity incentive plan and outstanding warrants to purchase common stock.

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, 2021.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders			
2009 Stock Incentive Plan (1)	2,622	$ 204.97	—
2014 Stock Incentive Plan	21,368	$ 158.60	16,620
2017 Stock Incentive Plan	38,227	$ 18.51	19,018
2018 Stock Incentive Plan (2)	2,847,755	$ 6.09	323,259
Total	2,909,972	$ 7.55	358,897

(1) The 2009 Stock Incentive Plan terminated, such that no further awards are available for issuance under this plan. Outstanding awards under this plan continue in accordance with the respective terms of such grants.
(2) The 2018 Stock Incentive Plan has 750,000 shares authorized for issuance which are subject to forfeiture if not approved at the 2022 annual shareholder meeting.

Recent Sales of Unregistered Securities

Except as previously disclosed in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, we had no sales of unregistered equity securities during the year ended December 31, 2021.

Purchase of Equity Securities

We have not purchased any of our equity securities during the period covered by this Annual Report.

Item 6. ***[Reserved]***

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, 2021 and December 31, 2020 found in this Annual Report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward-looking statements by using words such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report.

Company Overview

We are a biopharmaceutical company primarily engaged in the development of immune therapies and vaccines. Our gp96 platform is designed to activate the immune system. This platform has broad applications in cancer and infectious disease. Our platform leverages gp96's role as a natural molecular warning system that presents antigens to the immune system. HS-110 (viagenpumatucel-L) is our first allogeneic ("off-the-shelf") cell line biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's T-cells to destroy cancer. HS-130 is an allogeneic cell line engineered to express the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T-cells, with the potential to augment antigen-specific CD4+ T-cell and CD8+ T-cell responses. We have initiated development of a new COVID-19 vaccine program under our Zolovax, Inc. subsidiary that utilizes our gp96 platform to secrete SARS-CoV-2 antigens. Our subsidiary Pelican Therapeutics, Inc. ("Pelican"), is developing PTX-35, a novel T-cell co-stimulator agonist antibody targeting DR3/TNFRSF25 for systemic administration.

These programs are designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. We have completed the following clinical milestones: patient enrollment completed for our HS-110 Phase 2 non-small cell lung cancer (NSCLC) clinical trial, enrollment and dosing of fifteen patients in our HS-130 Phase 1 clinical trial, and dosing of fifteen patients in our PTX-35 Phase 1a clinical trial.

We are also providing pre-clinical, CMC development, and administrative support for these programs, while constantly focusing on protecting and expanding our intellectual property in areas of strategic interest. As we advance our clinical programs, we are in close contact with our CROs and clinical sites to monitor the impact of COVID-19 on our studies, current timelines, and costs.

In an effort to decrease our dependence upon third party manufacturers and enhance efficiency, we are designing and building a cGMP facility in San Antonio, Texas for bioanalytics, process development and manufacturing activities. We will also offer external customers fee-for-service contracting after completion of the build out.

Our gp96 Platform includes *ImPACT*® and *ComPACT*™ which are designed to activate and expand tumor antigen specific "killer" T-cells to destroy a patient's cancer. By turning immunologically "COLD tumors HOT," we believe our platform will become an essential component of the immuno-oncology regimen to enhance the effectiveness and durability of checkpoint inhibitors and other cancer therapies, thereby improving outcomes for those patients less likely to benefit from checkpoint inhibitors alone.

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

Unlike many other "patient specific" or autologous immunotherapy approaches, our drugs are fully allogenic, "off-the-shelf" products which means that we can administer drug immediately without the extraction of blood or tumor tissue from each patient or the creation of an individualized treatment based on patient materials. Our gp96 product candidates are produced from allogeneic cell lines expressing tumor-specific proteins common among cancers. Because each patient is dosed with the same medication, we believe that our immunotherapy approach offers superior speed to initiation, logistical, manufacturing and importantly, cost benefits, compared to "personalized" precision medicine approaches.

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

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

ComPACT™, our second gp96-based program, delivers antigen-driven T-cell activation and specific co-stimulation in a single product by providing specific co-stimulation to enhance T-cell activation and expansion. This approach has the potential to simplify combination immunotherapy development for oncology patients, as it is designed to deliver the gp96 heat shock protein and a T-cell co-stimulatory fusion protein (OX40L) as a single therapeutic, without the need for multiple, independent biologic products. This dual approach has several potential advantages including: (a) enhanced activation of antigen-specific CD8+ T-cells; (b) boosting the number of antigen-specific CD8+ and CD4+ T-cells compared to OX40L alone; (c) stimulation of T-cell memory function to remain effective after treatment, even if the cancer comes back; (d) demonstration of less toxicity, as the source of cancer associated antigens and co-stimulator are supplied at the same time locally in the draining lymph nodes, which drives targeted, cancer specific immunity towards the tumor rather than throughout the body; and (e) simplification of combination cancer immunotherapy versus systemic co-stimulation with conventional monoclonal antibodies (mAbs).

Pelican, our subsidiary, is a biotechnology company focused on developing an agonist mAb, PTX-35, against a T-cell costimulatory receptor, DR3/TNFRSF25. PTX-35 has completed IND-enabling activities in preparation for a first-in-human (FIH) trial for oncology. Pelican has initiated its first clinical trial site for PTX-35 and began dosing patients in the Phase 1 clinical trial. PTX-35 is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. DR3/TNFRSF25 agonism has been shown to provide highly selective and potent stimulation of antigen experienced 'memory' CD8+ cytotoxic T-cells, which are the class of long-lived T-cells capable of eliminating tumor cells in patients. Due to the preferential specificity of PTX-35 to antigen experienced CD8+ T-cells, this agent represents a promising candidate as a T-cell co-stimulator in cancer patients.

When combined in preclinical studies with Heat's gp96 platform immunotherapies and an anti-PD-1 checkpoint inhibitor, PTX-35 has been shown to enhance antigen specific T-cell activation to eliminate tumor cells. Pelican is also developing other biologics that target DR3/TNFRSF25 for various immunotherapy approaches.

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

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

Recent Developments

On December 20, 2021, we entered into the Merger Agreement with Merger Sub, Elusys and Fortis Advisors LLC, pursuant to which, subject to certain conditions, we will acquire Elusys through the Merger of Merger Sub with Elusys. The acquisition of Elusys has not been completed and is subject to several conditions. See "Potential Elusys Acquisition" below for additional information regarding the Merger Agreement.

Funding/Liquidity

We commenced active operations in June 2008. Our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates and undertaking preclinical and clinical studies of our most advanced product candidates. To date, we have primarily financed our operations with net proceeds from the sale of our securities including, our July 2013 initial public offering in which we received net proceeds of $24.3 million, our March 2015 public offering in which we received net proceeds of $11.1 million, our March 2016 public offering in which we received net proceeds of $6.1 million, an additional $3.9 million from the exercise of warrants, our March 2017 public offering in which we received net proceeds of approximately $4.1 million, our November 2017 public offering in which we received net proceeds of approximately $2.4 million, our May 2018 public offering in which we received net proceeds of approximately $18.8 million and an additional $4.8 million from the exercise of warrants, our November 2018 public offering in which we received net proceeds of approximately $12.7 million and our January 21, 2020 public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $6.4 million. As of December 31, 2021, we have received $13.7 million in grant funding from the CPRIT Grant through Pelican. We have also raised an aggregate of $140.1 million through at-the-market offerings, including $25.6 million during the year ended December 31, 2021. Cash and cash equivalents at March 9, 2022 were approximately $86.8 million. As of December 31, 2021, we had an accumulated deficit of $165.7 million. We had net losses of $35.4 million and $26.4 million for the years ended December 31, 2021 and 2020, respectively.

We expect to continue to incur significant expenses and continued losses from operations for the foreseeable future and we do not anticipate to generate revenue from any product sales for several years, including Anthim upon consummation of the pending acquisition of Elusys, which will take several years to conduct full scale manufacturing for commercial sale and obtain required regulatory approvals and anticipate only generating minimal revenue from our manufacturing facility in the next few years until the facility is fully operational and we develop a customer base. 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 add to our product candidate pipeline and continue construction of the cGMP manufacturing facility in San Antonio, Texas and related equipment expenses. Furthermore, we anticipate increased costs associated with the manufacture of Anthim, upon completion of the pending Elusys acquisition, and the increase in headcount upon completion of the pending acquisition of Elusys. In addition, if we expand our operations we will incur additional expenses which could be significant. Furthermore, 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. As currently planned, we expect to have sufficient funds to fund our operations into 2024. We will need to obtain substantial additional future funding in connection with our future planned clinical trials, the manufacturing facility that we are building out in San Antonio, Texas, full scale manufacturing of Anthim upon completion of the pending Elusys acquisition, and any new opportunities we may pursue. We also expect our general and administrative expenses to increase upon the consummation of our planned acquisition of Elusys due to increased headcount and cash consideration and other expenses set forth in the Merger Agreement that we have agreed to pay. Adequate additional financing may not be available to us on acceptable terms, or at all. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which include sales of our common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We 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;
- Derivative financial instruments;
- Research and development costs, including clinical and regulatory cost; and
- Recent accounting pronouncements.

Grants Receivable and Revenue

Our 2021 and 2020 revenue primarily consisted of research funding from our CPRIT Grant. Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the award have been met for collection. Proceeds received prior to the costs being incurred or the conditions of the award being met are recognized as deferred revenue until the services are performed and the conditions of the award are met. When grant funds are received after costs have been incurred, the Company records revenue and a corresponding grants receivable until grant funds are received.

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. See Note 7 regarding impairment at December 31, 2021. The IPR&D assets were acquired on April 28, 2017 when we acquired Pelican.

Goodwill and In-Process R&D Impairment

Goodwill and in process R&D may result from our business acquisitions. In-process research and development is considered an indefinite-lived intangible asset and is not subject to amortization until the associated projects are completed or terminated. Indefinite-lived intangible assets are tested for impairment annually, when events or changes in circumstances indicate the asset may be impaired, or when their useful lives are determined to be no longer indefinite.

We test goodwill and in-process R&D for impairment each year as of April 1, or more frequently should a significant impairment indicator occur. As part of the impairment test, we may elect to perform an assessment of qualitative factors. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit, including goodwill, is less than its carrying amount, or if we elect to bypass the qualitative assessment, we would then proceed with the impairment test. The impairment test involves comparing the fair values of the reporting units to their carrying amounts. If the carrying amount of a reporting unit exceeds its fair value, we recognize a goodwill loss in an amount equal to any excess.

Determining the fair value of a reporting unit is judgmental in nature and involves the use of significant estimates and assumptions. We forecast discounted future cash flows at the reporting unit level using risk-adjusted discount rates and estimated future revenues, launch costs and operating costs, which take into consideration expectations of competitive, business, and economic environments. We also identify similar publicly traded companies and develop a correlation, referred to as a multiple, to apply to the operating results of the reporting units. These combined fair values are then reconciled to the aggregate market value of our common stock on the date of valuation, while considering a reasonable control premium.

Determining the fair value of IPR&D is judgmental in nature and involves the use of significant estimates and assumptions. We forecast discounted future cash flows risk-adjusted discount rates and estimated future revenues, launch costs and operating costs, which take into consideration expectations of competitive, business, and economic environments. The fair value is then compared to the carrying value and if the carrying value exceeds fair value an impairment charge is recognized.

Changes in market demand, fluctuations in the markets in which we operate, the volatility and decline in the worldwide equity markets, and a decline in our market capitalization could unfavorably impact the remaining carrying value of our goodwill and in process R&D, which could have a significant effect on our current and future results of operations and financial position.

Income Tax

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

In accordance with FASB ASC 740, Accounting for Income Taxes, we reflect in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered ‘more-likely-than-not’ that the position taken will be sustained by a taxing authority. As of December 31, 2021 and 2020, we had no unrecognized income tax benefits and correspondingly there is no impact on our effective income tax rate associated with these items. Our policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2021 and 2020, we had no such accruals.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a probability-weighted income approach 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 as they occur. 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 use an average historical stock price volatility of our own data plus an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms. 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 remaining 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.

Derivative Financial Instruments

We issued common stock warrants in connection with the execution of certain equity financings. The fair value of the warrants, which were deemed to be derivative instruments, was recorded as a derivative liability under the provisions of ASC Topic 815 Derivatives and Hedging ("ASC 815") because they are not considered indexed to the Company's own stock. Subsequently, the liability is adjusted to fair value as of the end of each reporting period and the changes in fair value of derivative liabilities are recorded in the consolidated statements of operations and comprehensive loss under the caption "Change in fair value of warrant liability." See Note 2 to the consolidated financial statements for additional information.

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, in-process R&D impairment, 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 June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses which requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. This standard is effective for fiscal years beginning after December 15, 2022 and we are currently evaluating the expected impact of this standard but do not expect it to have a material impact on its consolidated financial statements upon adoption.

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This ASU simplifies the accounting for convertible instruments. This ASU also requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. The ASU is effective for annual periods beginning after December 15, 2021 with early adoption permitted. We are currently evaluating the impact this standard will have on our consolidated financial statements.

RESULTS OF OPERATIONS

Year Ended December 31, 2021 and 2020

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 was required to raise $7.6 million in matching funds over the life of the project.

As of December 31, 2021, CPRIT has provided $13.7 million of the total $15.2 million grant. The remaining $1.5 million will become available on a reimbursement basis, rather than in advance of expending the funds as in prior grant years. As of December 31, 2021, we have provided Pelican with approximately $7.6 million which was used to satisfy Pelican's matching fund obligation under the first four years of the CPRIT Grant.

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 $2.1 million for the year ended December 31, 2021 for qualified expenditures under the grant. We recognized $2.8 million grant revenue related to CPRIT during the year ended December 31, 2020. As of December 31, 2021, we have a remaining $1.5 million to be awarded, on a reimbursement basis, after the Company has fulfilled every requirement of the grant and the grant has been approved to be finalized. Funds received are reflected in deferred revenue as a liability until revenue is earned. When grant funds are received after costs have been incurred, the Company records revenue and a corresponding grants receivable. Grant revenue is recognized when qualifying costs are incurred.

Operating Expenses

Total operating expenses for the years ended December 31, 2021 and 2020, were $37.5 million and $29.1 million, respectively. For the year ended December 31, 2021 operating expenses are primarily comprised of research and development, general and administrative expenses, goodwill impairment loss, and a change in the fair value of contingent consideration related to Pelican. Research and development expenses were $18.8 million, general and administrative expenses were $16.8 million, goodwill impairment loss was $1.5 million, and the change in fair value of contingent consideration was $0.4 million for the year ended December 31, 2021 as compared to research and development expenses of $12.9 million, general and administrative expenses of $14.9 million, and the change in fair value of contingent consideration of $1.2 million for the year ended December 31, 2020. For the year ended December 31, 2021, research and development expenses represented approximately 50% of operating expenses, general and administrative expenses represented approximately 45%, goodwill impairment loss represented approximately 4%, and change in fair value of contingent consideration 1% of operating expenses. For the year ended December 31, 2020, research and development expenses represented approximately 45% of operating expenses, general and administrative expenses represented approximately 51%, and change in fair value of contingent consideration 4% of operating expenses.

Research and development expense

Research and development expenses increased to $18.8 million from $12.9 million for the years ended December 31, 2021 and December 31, 2020. The components of R&D expense are as follows, in millions:

	For the Year Ended December 31,	
	2021	2020
Programs		
HS-110	$ 1.7	$ 1.3
HS-130	0.9	0.8
PTX-35	2.9	2.0
COVID-19	1.8	0.5
RapidVax	0.1	—
Other programs	0.1	0.5
In-process R&D Impairment	2.4	—
Unallocated research and development expenses	8.9	7.8
	$ 18.8	$ 12.9

- HS-110 increased by $0.4 million, reflecting the current period mix of development activities, primarily due to increased costs associated with the transition of patients from active treatment into long-term follow-up, and increased manufacturing costs.
- HS-130 expense increased by $0.1 million due to the completion of enrollment of patients, third-party regulatory consulting, and investigator site payments for the ongoing Phase 1 clinical trial.
- PTX-35 expense increased by $0.9 million, primarily consisting of manufacturing development and patient dosing.
- COVID-19 program increased by $1.3 million, which primarily represents an increase in sponsored research agreement costs and manufacturing costs.
- RapidVax was initiated in Q4 2021 and primarily consists of consulting costs.
- Other programs expenses decreased by $0.4 million and include preclinical costs associated with our Zika program, T-cell costimulatory programs, and laboratory supplies.
- In-process R&D had a $2.4 million impairment loss recorded in 2021.
- Unallocated research expenses increased by $1.1 million primarily from increased clinical and CMC consulting expenses and Skunkworx lab and personnel costs.

General and administrative expense

General and administrative expense increased approximately 13% to $16.8 million for the year ended December 31, 2021 compared to $14.9 million for the year ended December 31, 2020. The increase of $1.9 million is primarily due to the increase in salaries, D&O insurance expense, and legal fees.

Change in fair value of contingent consideration

We reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. The change in the fair value of contingent consideration was $0.4 million for the year ended December 31, 2021 compared to the change in fair value of contingent consideration of $1.2 million for the year ended December 31, 2020. The decrease in fair value for the year ended December 31, 2020 was primarily due to the payment of the first milestone to the Pelican stockholders in 2020 and fewer adjustments to the probability of achieving milestones and holding timelines constant.

Goodwill impairment loss

During the year ended December 31, 2021, we experienced a sustained decline in the quoted market price of our common stock and as a result we determined that it was more likely than not that the carrying value of goodwill exceeded its estimated fair value. Accordingly, we performed an impairment analysis using the income approach. This analysis required significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital. As a result, we recorded a goodwill impairment loss of $1.5 million on the goodwill during the year ended December 31, 2021. No impairment was recorded during the year ended December 31, 2020.

Change in fair value of warrant liability

During the year ended December 31, 2020, we issued common stock warrants in connection with the execution of certain equity financings. The fair value of the warrants, which were deemed to be derivative instruments, were recorded as a derivative liability and was adjusted to fair value at the end of the reporting period resulting in $1.0 million of warrant expense. The adjustment to the fair value of the derivative liability for the year ended December 31, 2021 was de minimis.

Interest Income

Interest income was $0.8 million for the year ended December 31, 2021 compared to $0.6 million for the year ended December 31, 2020. The increase is due to the investment in various short-term financial instruments that generated interest income during the year ended December 31, 2021.

Other (expense) income, net

Other income (expense), net was $1.0 million expense for the year ended December 31, 2021, compared to $0.3 million income for the year ended December 31, 2020. This change was primarily due to unrealized losses associated with our short-term investments.

Income tax benefit (expense)

Income tax benefit of $0.1 million for the year ended December 31, 2021 related to the ASC 350 impairment charge against our IPR&D asset. Since that is an indefinite-lived intangible asset, we recognized a net deferred tax liability of $0.2 million due to the asset value decreasing.

Net loss attributable to Heat Biologics, Inc.

We had a net loss attributable to Heat Biologics, Inc. of $35.1 million, or ($1.41) per basic and diluted share for the year ended December 31, 2021 compared to a net loss attributable to Heat Biologics, Inc. of $26.0 million, or ($1.63) per basic and diluted share for the year ended December 31, 2020.

BALANCE SHEET AS OF DECEMBER 31, 2021 AND 2020

Short-term Investments. Short-term investments were $88.3 million as of December 31, 2021 compared to $100.8 million as of December 31, 2020. The decrease is primarily due the sale of investments and transferring the cash to fund clinical trials and other operations.

Prepaid Expenses and Other Current Assets. Prepaid expenses and other current assets was approximately $2.9 million as of December 31, 2021 and $1.8 million as of December 31, 2020. The $1.1 million increase was primarily attributable to our upfront payments to certain vendors for our clinical trials related to PTX-35.

Property, Plant & Equipment. PP&E was approximately $2.2 million as of December 31, 2021, and $0.7 million as of December 31, 2020. The increase is attributed to a $1.5 million increase in lab equipment purchased for Heat and Skunkworx.

Grants Receivable. We had grants receivable of $1.3 million as of December 31, 2021 compared to no grants receivable as of December 31, 2020. The CPRIT grant will award the remaining grant funds, on a reimbursement basis, after Heat has fulfilled every requirement of the grant and the grant has been approved to be finalized. The receivable relates to reimbursable costs incurred related to PTX-35.

Other assets. Other assets was approximately $12.2 million and $0 as of December 31, 2021 and 2020, respectively. The $12.2 million increase is directly attributable to equipment purchases in 2021 for Scorpion's new facility in San Antonio, Texas, which is expected to commence operations in the second quarter of 2022.

In-Process R&D. As of December 31, 2021 and 2020, we had in-process R&D of $3.5 million and $5.9 million from our acquisition of Pelican, respectively. The carrying value of this asset decreased by $2.4 million due to an in-process R&D impairment charge for the year ended December 31, 2021.

Goodwill. As of December 31, 2021 and December 31, 2020, we had goodwill of $0.0 million and $1.5 million, respectively, from our acquisition of Pelican. The carrying value of this asset decreased by $1.5 million due to a full impairment charge for the excess of the reporting unit's carrying value over its fair value in 2021.

Accounts Payable. Accounts payable was approximately $0.9 million and $1.1 million as of December 31, 2021 and December 31, 2020. Accounts payable remaining steady with only a $0.2 million decrease is due to payables for investigator site payments for our clinical trials remained steady.

Deferred Revenue. We had short term deferred revenue of $0 and $0.6 million as of December 31, 2021 and December 31, 2020, respectively. This short term deferred revenue represents proceeds received for the CPRIT grant but for which the costs had not been incurred or the conditions of the award had not been met. We had long term deferred revenue of $35,000 and $0.2 million as of December 31, 2021 and 2020. The decrease of $0.2 million was due to recognition of grant revenue from termination of a City of San Antonio economic development grant agreement for Pelican.

Accrued Expenses and Other Liabilities. Accrued expenses were approximately $2.4 million at December 31, 2021 compared to $1.6 million at December 31, 2020. The increase is primarily due to higher clinical expense accruals.

Operating and financing lease liabilities. Current and long term liabilities related to operating and finance leases was $1.9 million as of December 31, 2021 and $1.8 million as of December 31, 2020. These balances are related to our office lease and equipment leases.

Deferred Tax Liability. Deferred tax liability was approximately $0.2 million and $0.4 million for the years ended December 31, 2021 and December 31, 2020, respectively. The decrease is a result of the ASC 350 impairment charge against our IPR&D asset.

Contingent Consideration. As of December 31, 2021, we had contingent consideration of $3.3 million compared to $2.9 million for the year ended December 31, 2020 related to our acquisition of Pelican which is recorded on our consolidated balance sheets. This amount represents the fair value of future milestone payments to Pelican shareholders which were discounted in accordance with ASC 805. We perform an analysis on a quarterly basis and for the year ended December 31, 2021, we determined the change in the estimated fair value of the contingent consideration to be approximately $0.4 million due to the effect of the change in discount rate, probability of achieving milestones, and passage of time on the fair value measurement.

LIQUIDITY AND CAPITAL RESOURCES

Current and Future Financing Needs

Since our inception in June 2008, we have incurred significant losses and we have financed our operations with net proceeds from the private placement of our preferred stock, common stock and debt. Since our initial public offering, we have primarily financed our operations with net proceeds from the public offering of our securities and to a lesser extent,

the proceeds from the exercise of warrants. During May 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $18.8 million and after the closing of the offering, an additional $4.8 million from the exercise of 436,381 warrants issued in this offering. During November 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $12.7 million. For the year ended December 31, 2018 and 2019, we received net proceeds of approximately $3.8 million from sales of our common stock in at-the-market offerings. On January 21, 2020, we closed an underwritten public offering of shares of our common stock and warrants to purchase shares of our common stock pursuant to which we received net proceeds of approximately $6.4 million. For the year ended December 31, 2021, we received net proceeds of $25.6 million from the sale of 2,106,027 shares of our common stock in at-the-market offerings. As of December 31, 2021, we had an accumulated deficit of approximately $165.7 million. We had net losses of $35.4 million and $26.4 million for the years ended December 31, 2021 and 2020, respectively.

In order to promote efficiency and reduce our reliance on third-party vendors, we plan to enhance our in-house development of bioanalytic, process development and manufacturing capabilities and offer such services to third parties for fees. We have entered into a lease for a 20,144 square foot facility in San Antonio, TX to conduct such services and
are currently building the facility. Our proposed expansion in Texas is part of a company-wide-growth strategy to enhance efficiency and decrease our dependence on third-party vendors as we advance our clinical trials and general research and development. The future forecasted investment to build out the facility with labs, equipment, and staff will be approximately $23.5 million, without taking into account federal new market tax credits based on the location in San Antonio, federal and state historical tax credits based on the historical designation of the facility, as well as city and county tax abatement incentives with the City of San Antonio and Bexar County. Scorpion reimbursements to Merchants Ice, who is purchasing the equipment for the CDMO facility, has paid $12.2 million for equipment through the fourth quarter of 2021 and approximately $7.5 million is expected to be spent in the first quarter of 2022 is included in the $23.5 million. We intend to fund this initiative with current working capital. The potential value of tax credits and tax incentives to Scorpion are estimated to be up to approximately $4.5 million based on the total cost of the build out, employees hired, real property, and other factors. Operations at the facility are projected to commence by second quarter of 2022, and we expect to fill production capacity by transitioning our outsourced manufacturing and development to in-house immediately and followed by contracting with external customers. However, there can be no assurance that we will be successful in these new operations. As of February 28, 2022 we have spent $15.8 million on laboratory related manufacturing equipment for the San Antonio facility. We intend to meet our financing needs through multiple alternatives, including, but not limited to, cash on hand, additional equity financings, debt financings and/or funding from partnerships or collaborations and potential revenue, if any, from our planned development and manufacturing facility.

Furthermore, upon consummation of our pending acquisition of Elusys, we anticipate increased costs associated with the manufacture of Anthim and the increase in headcount due to the acquisition of Elusys. Pursuant to the terms of the Merger Agreement we agreed to cash consideration at Closing of $3 million plus additional expenses of $1.6 million that we were obligated to pay and are obligated to pay an additional $2 million, subject to adjustment upon attainment of certain milestones.

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Although we currently have sufficient funds to complete our Phase 2 clinical trials, as currently planned, and expect that we will have sufficient funds to fund our operations into 2024, we will need to obtain substantial additional future funding in connection with our future planned clinical trials, manufacture of Anthim, upon consummation of our pending acquisition of Elusys, and our manufacturing facility construction and set up.

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;

- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our expansion plans and cash needs of any new projects;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals;
- the receipt of grant funding if any;
- clinical laboratory development and testing;
- manufacturing facility construction costs and equipment costs; and
- manufacturing costs of Anthim upon consummation of the pending acquisition of Elusys.

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, such as through the Amended and Restated Common Stock Sales Agreement with B. Riley FBR, Inc. and Cantor Fitzgerald & Co., or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed. While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

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. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which include sales of our common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We will need to generate significant revenues to achieve profitability, and we may never do so. As of December 31, 2021, we had approximately $96.4 million in cash and cash equivalents and short-term investments.

Cash Flows

Operating activities. The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities during the year ended December 31 2021 was $38.1 million compared to $22.0 million during the same period in 2020. The increase was primarily due to an increased net loss of $9.0 million, a decrease in the change in fair value of common stock warrants of $1.0 million, a decrease in the change in fair value of contingent consideration of $0.8 million, an increase in other assets of 12.2 million.

Investing activities. Net cash provided by investing activities was $9.8 million during year ended December 31, 2021 compared to $95.4 million used during the same period in 2020. The increase is from the change in net purchases of short-term investment purchases and sales of $106.8 million from 2021 to 2020.

Financing activities. Net cash provided by financing activities was $25.5 million during the year ended December 31, 2021 compared to $119.3 million during the year ended December 31, 2020. The decrease of $93.8 million was primarily due to a $91.1 million net decrease of sales of our common stock through an at-the-market Common Stock Sales Agreement with B. Riley FBR, Inc. and Cantor Fitzgerald & Co., net of the decrease in related stock issuance costs of $2.4 million, partially offset by a public offering of shares that occurred in 2020 of $6.6 million.

On April 23, 2020, Heat and Pelican received loan proceeds of $0.7 million from Regions Bank, N.A, pursuant to the Paycheck Protection Program, or the PPP Loan, under the CARES Act, administered by the U.S. Small Business Administration. On April 28, 2020, we returned all $0.7 million in proceeds from the PPP Loan in order to make those funds available to other borrowers that may be in greater need.

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.

Additional In-Licensed Programs

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

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

Not applicable because we are a smaller reporting company.

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

See pages F-1 through F-32.

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

None.

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

Disclosure Controls and Procedures

Our management has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, our management, including the Principal Executive Officer and Principal Financial Officer has conducted an evaluation of the effectiveness of disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2021.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. Our internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of our internal control over financial reporting based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework* (2013). Based on the assessment, management concluded that, as of December 31, 2021, our internal controls over financial reporting were effective at the reasonable assurance level based on those criteria.

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

This Annual Report 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.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our last quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

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

Below is certain information regarding our directors and executive officers.

Name	Age	Position	Served as an Officer or Director Since
Jeffrey Wolf	58	Chairman of the Board of Directors, Chief Executive Officer and President	2008
William L. Ostrander	54	Chief Financial Officer and Secretary	2019
John Monahan, Ph.D.	75	Director	2009
John K.A. Prendergast, Ph.D.	68	Director	2016
Edward B. Smith, III	46	Director	2010

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

Mr. Wolf has served our Chairman of the Board of Directors, Chief Executive Officer and President since our inception. He founded Heat Biologics in August 2008. Mr. Wolf served from June 1997 to March 2011, as managing director at Seed-One Ventures, LLC a venture firm focused on launching and growing exceptional healthcare companies from the ground up. Since founding Seed-One, Mr. Wolf has founded and run several biomedical companies. Mr. Wolf's start-ups include Avigen, Inc., a gene therapy company where he was a co-founder and director; TyRx Pharma, a Princeton-based company focused on the development of bio-compatible polymers where he was a co-founder and Chairman and Elusys, where he was for several years a co-founder, Chairman and Chief Executive Officer; and Generation One, a company focused on mobile-based collaborative care, where he was the founder, Chairman and Chief Executive Officer. Mr. Wolf received his M.B.A. from Stanford Business School, his J.D. from New York University School of Law and his B.A. from the University of Chicago, where he graduated with honors in Economics. Mr. Wolf serves as a director of several Seed-One portfolio companies and serves as a director of Synthetic Biologics, Inc., a 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.

William L. Ostrander, ***Chief Financial Officer and Secretary***

Mr. Ostrander currently serves as our Chief Financial Officer, a position he was appointed to on January 4, 2021 and has served as our Secretary since September 25, 2019 when he joined our company as Vice President of Finance. Mr. Ostrander has over 22 years of experience in financial management at public and private companies. From November 2014 until joining our company, Mr. Ostrander served as Executive Director of Finance at Liquidia Technologies, Corporation, a publicly-traded biopharmaceutical company. Prior to that, he served as Senior Director of Finance and Accounting at KBI Biopharma, a biopharmaceutical contract services company. He also served as Manager of Finance at LexisNexis Risk Solutions, a data analytics solutions company. Prior to that, he served as Controller of Seisint Inc., a private information products company that was acquired by LexisNexis. He also served as Senior Manager, Finance and held other accounting and finance positions for Boca Research, a data communications hardware manufacturer. Mr. Ostrander holds a B.S. in Finance from Central Michigan University.

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

Dr. Monahan has served on our Board of Directors since November 2009. Dr. Monahan Co-Founded Avigen Inc. in 1992, a pharmaceutical company. Over a 12 year period as CEO of Avigen he raised over $235M in several private and public financings including its IPO. From 1989 to 1992, he was VP of R&D at Somatix Therapy Corp., and from 1985 to 1989 he was Director of Molecular & Cell Biology at Triton Biosciences Inc. Prior to that, from 1982 to 1985, he was Research Group Chief, Department of Molecular Genetics, Hoffmann-LaRoche AG. and from 1975 to 1977 he was an instructor at Baylor College of Medicine located in Houston, Texas. He received his Ph.D. in Biochemistry in 1974 from McMaster University in Canada and his B.Sc. from University College in Dublin, Ireland in 1969. Dr. Monahan is a Scientific Advisory Board member of Agilis Biotherapeutics, LLC. Dr. Monahan currently is a board member of Synthetic Biologics, Inc., and served as a scientific advisory consultant to Synthetic Biologics, Inc. from 2015 to November 10, 2020, prior to his appointment as a board member, and from 2010 through 2015 he was the Senior Executive Vice President of Research & Development at Synthetic Biologics, Inc He is also a board member of a number of Irish biotech companies including Genable Technologies Ltd., Cellix Ltd., Luxcel Biosciences Ltd., and GK Technologies, Inc. and from August 2016 until May 2021, also was a board member of Anixa Biosciences, Inc. (formerly ITUS Corporation).

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

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

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

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

Edward B. Smith, III, *Director*

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

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

Committees of the Board of Directors

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

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

* Dr. Prendergast serves as our independent Lead Director.

Audit Committee

Our common stock is listed on the NYSE American. Under the rules of NYSE American, 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 NYSE American, 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 NYSE American. 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 NYSE American 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 NYSE American rules. The primary purpose of the Audit Committee is to act on behalf of the Board of Directors in its oversight of all material aspects of our accounting and financial reporting processes, internal controls and audit functions, including our compliance with Section 404 of the Sarbanes-Oxley Act of 2002. Pursuant to its charter, our Audit Committee reviews on an on-going basis for potential conflicts of interest, and approves if appropriate, all our "Related Party Transactions." For purposes of the Audit Committee Charter, "Related Party Transactions" shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404. In addition, the Audit Committee reviews, acts on and reports to the Board of Directors with respect to various auditing and accounting matters, including the selection of the Company's independent registered public accounting firm, the scope of the annual audits, fees to be paid to the independent registered public accounting firm, the performance of the Company's independent registered public accounting firm and the accounting practices of the Company and the Company's internal controls and legal compliance functions. The Committee also reviews, prior to publication, our quarterly earnings releases and our reports to the Securities and Exchange Commission on Forms 10-K and 10-Q. The Audit Committee operates pursuant to a written charter adopted by the Board of Directors, which is available on the Company's website at *www.heatbio.com*. The charter describes the nature and scope of responsibilities of the Audit Committee.

Compensation Committee

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

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

Our Compensation Committee annually reviews the compensation program for our Chief Executive Officer and other members of senior management and then makes recommendations to the full board for determination. In each case, the Committee takes into account the results achieved by the executive, his or her future potential, and his or her scope of responsibilities and experience. During our fiscal year ended December 31, 2021, the Committee evaluated the performance of our executives and considered the compensation levels and equity programs at comparable companies and related industries and the analysis of its outside consultant before it made its compensation recommendations to the full board, including recommendations regarding salary increases, awards of cash bonuses and awards of stock options.

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

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

Nominating and Governance Committee

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

The functions performed by the Nominating and Governance Committee include:

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

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

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

When selecting a new director nominee, the Committee first determines whether the nominee must be independent for NYSE American 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*.

Ad Hoc Committees

From time to time we establish ad hoc committees to address particular matters. During 2021, we established a Special Committee comprised of Dr. Monahan, Dr. Prendergast, and Mr. Smith to review and negotiate the Merger Agreement with Elusys.

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 principal liaison between management and the independent directors of the Board. The Lead Director also:

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

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

Risk Oversight

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

Delinquent Section 16(a) Reports

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

Based solely on a review of the copies of such forms that were received by us, or written representations from certain reporting persons that no Forms 5 were required for those persons, we are not aware of any failures to file reports or report transactions in a timely manner during the year ended December 31, 2021.

Code of Business Conduct and Ethics

We have long maintained a Code of Business Conduct and Ethics that is applicable to all of our directors, officers and employees. We undertake to provide a printed copy of these codes free of charge to any person who requests. Any such request should be sent to our principal executive offices attention: Corporate Secretary. The code is posted on our website at www.heatbio.com.

Item 11. ***Executive Compensation***

We are a "smaller reporting company" and the following compensation disclosure is intended to comply with the requirements applicable to smaller reporting companies. Although the rules allow us to provide less detail about our executive compensation program, the Compensation Committee is committed to providing the information necessary to help stockholders understand its executive compensation-related decisions. Accordingly, this section includes supplemental narratives that describe the 2021 executive compensation program for our named executive officers.

Set forth below is the compensation paid or accrued to our Named Executive Officers during the years ended December 31, 2021 and December 31, 2020:

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards (9)	Options (9)	Other	Total
Jeffrey Wolf	2021	$ 539,623	$ 270,000	$ 2,633,525 (1)	$ 1,964,424 (2)	$ 500,000 (3)	$ 5,907,572
Chairman and Chief Executive Officer	2020	$ 440,406	$ 220,203	$ 910,800 (4)	$ 4,348,528 (5)	$ 500,000 (6)	$ 6,419,937
William L. Ostrander	2021	$ 274,817	$ 96,250	$ —	$ 451,602 (7)	$ —	$ 822,669
Chief Financial Officer	2020	$ 226,600	$ 45,321	$ —	$ 66,427 (8)	$ —	$ 338,348

(1) Mr. Wolf was issued 288,100 shares of restricted stock on January 4, 2021 and 246,305 shares of restricted stock on December 13, 2021.
(2) Mr. Wolf was issued 147,980 option awards on January 4, 2021, 42,216 option awards on August 2, 2021 for the subsidiary plans as described in Note 11 to the Company's audited consolidated financial statements for the years ended December 31, 2021 and 2020, 161,774 option awards on December 13, 2021 and 231,987 option awards on December 30, 2021. The December 31, 2021 option grant is subject to forfeiture if an amendment to the 2018 Stock Incentive Plan to increase the number of shares of common stock available for grant is not approved by our stockholders.
(3) This is a special bonus to cover the estimated taxes from the 246,305 restricted share award granted on December 13, 2021.
(4) Mr. Wolf was issued 282,857 shares of restricted stock on January 2, 2020.
(5) Mr. Wolf was issued 285,714 option awards on July 28, 2020 and 201,728 option awards on August 24, 2020 pursuant to a contract obligation in his employment agreement that entered into in 2009.
(6) This is a special bonus to cover the estimated taxes from the 288,100 restricted share award granted on January 4, 2021.
(7) Mr. Ostrander was issued 51,487 option awards on January 4, 2021, 2,127 option awards on August 2, 2021 for the subsidiary plans as described in Note 11, to the Company's audited financial statements for the years ended December 31, 2021 and 2020, and 68,807 option awards on December 13, 2021.
(8) Mr. Ostrander was issued 21,428 option awards on March 12, 2020.
(9) For all stock options and stock awards, the values reflect the aggregate grant date fair value computed in accordance with FASB ASC 718. Assumptions made in the calculation of these amounts are described in Note 11 to the Company's audited consolidated financial statements for the years ended December 31, 2021 and 2020.

Narrative Disclosure To Summary Compensation Table

Overview of Our Compensation Program

A. Philosophy and Objectives

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

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

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

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

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

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

- a base salary;

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

- long term equity awards.

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

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

- the value of all outstanding equity awards; and

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

B. Compensation Administration

Roles and Responsibilities of Compensation Committee

The primary purpose of the Compensation Committee is to conduct reviews of our general executive compensation policies and strategies and oversee and evaluate our overall compensation structure and programs. The Compensation Committee confirmed that total compensation paid to our Named Executive Officers during the year ended December 31, 2021, was reasonable and competitive. The following were our Named Executive Officers for the year ended December 31, 2021: Jeffrey Wolf, our Chief Executive Officer and William L. Ostrander, our Chief Financial Officer (collectively, our "Named Executive Officers"). Responsibilities of the Compensation Committee include, but are not limited to:

- Establishing on an annual basis performance goals and objectives for purposes of determining the compensation of our Chief Executive Officer and other senior executive officers, evaluating the performance

of such officers in light of those goals and objectives, and setting the compensation level for those officers based on this evaluation.

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

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

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

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

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

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

Use of Compensation Consultant

The Compensation Committee retained Meridian Compensation Partners, LLC ("Meridian"), a nationally-recognized global human resources consulting firm, as its independent compensation advisor in 2020 and 2021. Meridian principally provides analysis, advice and recommendations regarding named executive officer and non-employee director compensation as well as guidance and considerations on our long-term incentive program for all eligible employees including salary, bonus, benefits and equity awards for our executive officers and retainers, meeting fees and equity awards for our directors. Meridian reports to the Chairman of the Compensation Committee and has direct access to the other members of the Compensation Committee. Meridian does not provide any other services to the Company other than in its role as the Compensation Committee's independent advisor. The Compensation Committee has evaluated Meridian's reports and, as they considered appropriate to achieve the best interests of the Company and its stockholders, implemented the recommendations.

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

Role of the Chief Executive Officer

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

Compensation Committee Consideration of Shareholder Advisory Votes

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

C. Competitive Considerations

In making compensation decisions with respect to each element of compensation for our Named Executive Officers, the Compensation Committee believes that it is important to be informed as to the competitive market practices at similarly situated public companies. In setting 2021 target total direct compensation levels for our Named Executive Officers, the Compensation Committee relied in part on reports prepared by Meridian effective January 4, 2021. Meridian conducted a comprehensive assessment of our Named Executive Officer's pay program relative to a peer group of 17 similarly-situated public companies that were pre-revenue cancer therapeutics companies with market capitalizations between $150 million and $1.5 billion. The elements of the Named Executive Officer's pay programs assessed against peer group practices for 2021 included: (1) base salary, (2) target annual incentives (bonuses), (3) target total cash compensation, (4) long-term incentives and (5) target total direct compensation. In addition, Meridian also provided an analysis of our pay mix relative to peer group practices. Meridian's assessment included our Chief Executive Officer and Chief Financial Officer. The Compensation Committee considered the competitive market pay data of our peer group that was included in Meridian's analysis and relevant survey data when setting each Named Executive Officer's compensation.

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 interests with those of our stockholders.

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

D. Components of Compensation

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

1. Base Salaries

We provide our Named Executive Officers a competitive level base salary commensurate with their position, responsibilities and experience. In setting the base salary, the Compensation Committee considers a number of factors including, peer group market data, our company performance and each Named Executive Officer's role and responsibilities, experience and individual performance. We design base pay to be competitive in attracting and retaining top talent.

Initial base salaries for the Named Executive Officers were set by their initial respective employment contracts and are reviewed annually by the Compensation Committee. The Compensation Committee determined that our Chief Executive's Officer's and Chief Financial Officer's 2021 base salary levels were below market practice of our peer group; therefore

the base salaries were increased in January 2021. The 2020, 2021, and 2022 base salaries for our current Named Executive Officers are as follows:

Named Executive Officer	Base Salary 2020	Base Salary 2021	Base Salary 2022
Jeffrey Wolf, Chief Executive Officer	$ 440,406	$ 540,000	$ 561,600
William L. Ostrander, Chief Financial Officer	$ 226,600	$ 275,000	$ 350,000

2. Bonuses

For 2021, the Compensation Committee recommended to the full Board of Directors the following bonus payouts to our Named Executive Officers:

- Jeffrey Wolf bonus. The Board approved the Compensation Committee's recommendation that Mr. Wolf receive a $270,000 cash bonus (50% of gross salary). In addition, in recognition of Mr. Wolf's achievements in successfully financing our company and expanding the product development pipeline, the Board approved the Compensation Committee's recommendation that Mr. Wolf also receive a $500,000 cash bonus in 2021 to cover his estimated taxes with respect to a restricted stock award that he received on December 13, 2021.

- William Ostrander bonus. The Board approved the Compensation Committee's recommendation that Mr. Ostrander receive a $96,250 cash bonus (35% of gross base salary).

The employment agreement with Jeffrey Wolf that was in effect during 2020 and 2021 provided that he was eligible for a cash performance bonus of up to fifty percent (50%) of his base as well an equity bonus in the sole discretion of the Board of Directors, with the actual amount of any such bonus increased or decreased in the sole discretion of the Board of Directors. William L. Ostrander's offer letter that was in effect for 2020 provided for an annual bonus of up to twenty percent (20%) of his base and as well as an equity bonus in the sole discretion of the Board of Directors, with the actual amount of any such bonus increased or decreased in the sole discretion of the Board of Directors. The cash performance bonus was increased to thirty percent (30%) when he was promoted to Chief Financial Officer effective January 4, 2021 and increased to thirty five percent (35%) in December 2021. 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

A substantial portion of the Named Executive Officer's total compensation is in the form of equity-based compensation to encourage retention and better align the interests of the Named Executive Officers with the stockholders. The Compensation Committee determined to grant a combination of stock options and restricted stock awards to the current Named Executive Officers and other key employees as the primary long-term incentive vehicles.

In 2020 and 2021 the Compensation Committee determined the size of equity awards granted to the Named Executive Officers based on the following factors: accounting impact, peer group market data, our company performance and each Named Executive Officer's position, role and responsibilities, experience, tenure, individual performance and pro forma percent ownership. In addition, the Compensation Committee considered that there was a lack of realizable value from their prior awards since substantially all of the prior awards were of significant low value and/or underwater or held low value. The Compensation Committee also sought to better align the Chief Executive Officer's equity ownership interest in our company with that of other chief executive officers of our peer group companies. The Compensation Committee determined in January 2021 and December 2021 to grant a combination of options and restricted stock awards to the Chief Executive Officer and options to the Chief Financial Officer.

In January 2021, Jeffrey Wolf was granted 288,100 restricted stock awards as part of his long-term incentive compensation for the year ended January 2021. On December 13, 2021, Mr. Wolf was also awarded 246,305 shares of restricted common stock, half of which vests immediately and the remaining half vests on January 1, 2022. The 246,305 shares of restricted

stock were awarded pursuant to the terms of an amended and restated restricted stock agreement.The restricted stock awards will vest 50% immediately and 50% on the one-year anniversary of the grant date. The restricted stock agreements with respect to the foregoing grants, among other things, prohibit transfers of the restricted stock prior to the two-year anniversary of the grant date other than by will, laws of descent and distribution and in the event of death. In addition, sales or transfers made after the two year anniversary of the grant date are subject to the right of us to buy back the stock at any time that the holder desires to sell the restricted stock at a price equal to the lower of the closing price per share and 17 times the closing price per share on the date of grant with respect to the 2020 and 2021 grants and 10 times the closing price per share on the date of grant with respect to the 2021 grants. In January 2021, Mr. Wolf was also granted an option to purchase up to 147,980 shares of common stock that vest on the two-year anniversary of the grant date. On December 13, 2021 and December 31, 2021, Mr. Wolf was awarded an option to purchase 161,774 and 231,987 shares of our common stock, respectively.

On December 13, 2021, Mr. Ostrander was awarded a ten-year option to purchase 68,807 shares of our common.Mr. Ostrander was issued 51,487 option awards on January 4, 2021.

In July and August 2020, Mr. Wolf was granted additional option awards to purchase 285,714 and 201,728 shares of common stock, respectively pursuant to the terms of his employment agreement entered into in 2009, which provided for such grant upon achievement of the milestone of our market capitalization being at least $500 million for at least 15 business days. These options vested upon issuance and are exercisable through the tenth anniversary of the date of grant.

On August 2, 2021, the Board of Directors adopted the Heat Biologics, Inc. 2021 Subsidiaries Stock Incentive Plan (the “SSIP”). The SSIP is designed to compensate employees of our subsidiaries based on their responsibilities and for their contributions to the successful achievement of certain corporate goals and objectives of such subsidiaries and to share the success and risks of such subsidiaries based upon achievement of business goals. In addition, in August we issued to Mr. Wolf options under the SSIP to purchase 10,526, 10,638, 10,526 and 10,526 shares of common stock of Skunkworx, Scorpion, Abacus, and Blackhawk, respectively and we issued Mr. Ostrander 2,127 shares the common stock of Scorpion, all subject to forfeiture if the Subsidiary Plan was not approved by our stockholders at our annual meeting so stockholders. At our Annual Meeting of Stockholders held on September 15, 2021, the SSIP was approved by our stockholders. Skunkworx, Scorpion, Abacus, and Blackhawk currently have 200,100, 200,100, 200,000 and 200,000 shares outstanding.

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.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2021)

	Option Awards				Stock Awards	
Name and Principal Position	**Number of securities underlying unexercised options/ exercisable**	**Number of securities underlying unexercised options/ unexercisable**	**Option exercise price**	**Option expiration date**	**Number of shares or units of stock that have not vested**	**Market value of shares or units of stock that have not vested**
Jeffrey Wolf	1,428 (1)	—	$ 603.40	06/11/2024	—	—
Chairman and	178 (2)	—	$ 317.10	1/12/2025	—	—
Chief Executive Officer	1,343 (3)	—	$ 172.90	1/11/2026	—	—
	1,071 (4)	—	$ 60.20	12/30/2026	—	—
	1,785 (5)	—	$ 60.90	1/03/2027	—	—
	8,331 (6)	177	$ 27.79	1/07/2028	—	—
	102,856 (7)	11,429	$ 7.42	1/02/2029	—	—
	285,714 (8)	—	$ 14.49	7/28/2030	—	—
	201,728 (9)	—	$ 8.40	8/24/2030	—	—
	— (10)	147,980	$ 5.67	1/04/2031	—	—
	3,933 (11)	6,705	$ 1.30	8/02/2031	—	—
	3,892 (12)	6,634	$ 1.67	8/02/2031	11,429 (13)	$ 34,744 (13)
	3,892 (14)	6,634	$ 0.01	8/02/2031	12,858 (15)	$ 39,088 (15)
	3,892 (16)	6,634	$ 0.01	8/02/2031	84,858 (17)	$ 171,979 (17)
	— (18)	161,774	$ 4.06	12/13/2031	144,050 (19)	$ 437,912 (19)
	— (20)	231,987	$ 4.06	12/30/2031	123,153 (21)	$ 374,385 (21)
William L. Ostrander	6,026 (22)	4,688	$ 3.64	9/25/2029	—	—
Chief Financial Officer	9,374 (23)	12,054	$ 4.20	3/12/2030	—	—
	17,162 (24)	34,325	$ 5.67	1/04/2031	—	—
	787 (25)	1,340	$ 1.30	8/02/2031	—	—
	— (26)	68,807	$ 4.06	12/13/2031	—	—

(1) All shares are fully vested as of January 2016.
(2) All shares are fully vested as of December 2018.
(3) All shares are fully vested as of December 2019.
(4) All shares are fully vested as of December 2020.
(5) All shares are fully vested as of January 2021.
(6) Issued January 7, 2018, these shares vest over a 46-month period and will be fully vested in January 2022.
(7) Issued January 2, 2019, 57,142 shares vested on January 2, 2019; 34,285 shares vested on January 2, 2020; 11,429 shares vested on January 2, 2021 and 11,429 shares vest on January 2, 2022.
(8) All shares vested on July 28, 2020.
(9) All shares vested on August 24, 2020.
(10) Issued January 4, 2021, these shares fully vest on January 4, 2023.
(11) Issued August 2, 2021, these Scorpion subsidiary plan option shares vest 1,282 shares on October 15, 2021; 9,356 over a 10-month period and will be fully vested in August 2022.
(12) Issued August 2, 2021, these Skunkworx subsidiary plan option shares vest 1,282 shares on October 15, 2021; 9,258 over a 10-month period and will be fully vested in August 2022.
(13) Issued January 2, 2019, 57,142 restricted stock units vested January 2, 2019; 34,286 vested January 2, 2020; 11,428 vested January 2, 2021; and 11,429 vest January 2, 2022. Amount represents the value of shares at December 31, 2021. Market value based on closing price of the common stock of $3.04 on December 31, 2021.
(14) Issued August 2, 2021, these Abacus subsidiary plan option shares vest 1,282 shares on October 15, 2021; 9,258 over a 10-month period and will be fully vested in August 2022.

(15) Issued December 30, 2019, 64,285 restricted stock units vested December 30, 2019; 38,571 vested December 30, 2020; 12,857 vested December 30, 2021; and 12,857 vest December 30, 2022. Amount represents the value of shares at December 31, 2021. Market value based on closing price of the common stock of $3.04 on December 31, 2021.
(16) Issued August 2, 2021, these Blackhawk subsidiary plan option shares vest 1,282 shares on October 15, 2021; 9,258 over a 10-month period and will be fully vested in August 2022.
(17) Issued January 2, 2020, 141,428 restricted stock units vested January 2, 2020; 84,858 vested January 2, 2021; 28,285 vest January 2, 2022; and 28,286 vest January 2, 2023. Amount represents the value of shares at December 31, 2021. Market value based on closing price of the common stock of $3.04 on December 31, 2021.
(18) Issued December 13, 2021, these shares fully vest on December 13, 2023.
(19) Issued January 4, 2021, 144,050 restricted stock units vested January 4, 2021; 144,050 vest January 4, 2022. Amount represents the value of shares at December 31, 2021. Market value based on closing price of the common stock of $3.04 on December 31, 2021.
(20) Issued December 30, 2021, these shares fully vest on December 30, 2023.
(21) Issued December 13, 2021, 123,052 restricted stock units vested December 13, 2021; 123,053 vest January 1, 2022. Amount represents the value of shares at December 31, 2021. Market value based on closing price of the common stock of $3.04 on December 31, 2021.
(22) Issued September 25, 2019, these shares vest over a 48-month period and will be fully vested in September 2023.
(23) Issued March 12, 2020, these shares vest over a 48-month period and will be fully vested in March 2024.
(24) Issued January 4, 2021, 17,162 shares vested on January 4, 2021; 17,162 vest on January 4, 2022; and 17,163 vest on January 4, 2023.
(25) Issued August 2, 2021, these Scorpion subsidiary plan option shares vest 1,282 shares on October 15, 2021; 9,356 over a 10-month period and will be fully vested in August 2022.
(26) Issued December 13, 2021, these shares vest over a 48-month period and will be fully vested in December 2025.

Employment Agreements

On December 18, 2009, we entered into an employment agreement with Jeffrey Wolf to act as our Chief Executive Officer, which agreement was amended on November 22, 2011, and further amended on each of January 20, 2014, January 11, 2016, January 1, 2017 and January 2, 2020. Pursuant to the employment agreement in effect during 2020, Mr. Wolf received an annual base salary of $540,000 per year. He was also eligible to receive, at the sole discretion of the board, an additional cash performance-based bonuses equal to up to 50% of his then outstanding base salary at the end of each year and a discretionary equity award, with the actual amount of his bonus to be increased or decreased in the sole discretion of the Board of Directors. In addition, he was also eligible 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 $500 million for at least 15 business days, which milestone was achieved in July 2020.

On January 4, 2021, we entered into a new employment agreement with Jeffrey Wolf (the “Wolf Agreement”) to continue to serve as our Chief Executive Office and President, which agreement replaces the employment agreement that we had entered into with Mr. Wolf on December 18, 2009, as amended on November 22, 2011, and further amended on each of January 20, 2014, January 11, 2016, January 1, 2017 and January 2, 2020. Pursuant to the terms of the Wolf Agreement, Mr. Wolf will receive an annual base salary of $540,000 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 in the sole discretion of the Board of Directors. In addition, he is to receive (i) an incentive cash bonus in an amount equal to 2% of the Transaction Consideration (as defined in the agreement) paid in connection with the consummation of a Change in Control (as defined in the agreement), provided that such Change in Control results in the stockholders of the Company receiving (or being entitled to receive, whether upon the consummation of the Change in Control or at a future date) transaction consideration worth at least 125% of the average closing trading price of the Company’s common stock during the 20 trading-day period immediately preceding the consummation of the Change in Control and (ii) an equity bonus in the form of additional stock options or restricted stock units or shares of restricted stock equal to 2% of the total fully-diluted equity of the Company if the market capitalization of the Company is equal to or exceeds a valuation of $500 million or more for fifteen (15) business days or longer. In addition, subject to certain condition, Mr. Wolf may also be entitled to receive equity in newly formed subsidiaries of the Company. If the Wolf Agreement is terminated for death or disability (as defined in the Wolf

Agreement), he (or his estate in the event of death) will receive any unpaid base salary through the date of death or disability, any unpaid target bonus earned through date of termination and he shall be entitled to exercise any vested awards for the shorter of 24 months after termination and the remaining term of the award. If Mr. Wolf's employment is terminated by us other than for Cause (as defined in the agreement) or by him for Good Reason (as defined in the Wolf Agreement), he will receive a payment of an amount equal to one (1) times his annual base salary plus his annual target bonus amount for the year of termination assuming payment in full of the annual target bonus, accelerated vesting of all unvested equity awards, extension of the time period in which to exercise awards equal to the lesser of 24 months after termination or the remaining term of the award and payment of COBRA premiums for the earlier or twelve months, the date he becomes eligible for other group benefits or his rights to COBRA expire. In addition, in the event the Company terminates Mr. Wolf's employment upon or at any time in connection with a Change of Control Transaction (as defined in the Wolf Agreement), Mr. Wolf is entitled to a lump sum cash payment equal to 24 months of his current base pay, a cash payment equal to a pro-rated amount of his target annual target bonus for the year preceding termination, payment in full for COBRA for 12 months following termination and immediate vesting of the unvested portion of any outstanding equity awards and a period to exercise the awards equal to the lesser of 12 months after termination or the remaining term of the award. If within one year after the occurrence of a Change in Control, the Executive terminates his employment for Good Reason or the Company terminates his employment for any reason other than death, disability of cause Mr. Wolf is entitled to a lump sum cash payment equal to 24 months of his current base pay, a cash payment equal to his full target annual target bonus, payment in full for COBRA for 12 months following termination and immediate vesting of the unvested portion of any outstanding equity awards and a period to exercise the awards equal to the lesser of 24 months after termination or the remaining term of the award. Under the Wolf Agreement, Mr. Wolf has also agreed to non-competition provisions.

Effective September 24, 2019 we entered into an offer letter with Mr. Ostrander to serve as our Vice President of Finance and Secretary. Effective January 4, 2021, Mr. Ostrander, was promoted to Chief Financial Officer. In connection with Mr. Ostrander's new role as our Chief Financial Officer, effective January 4, 2021, we entered into an amendment (the "Ostrander Amendment") to the offer letter, dated September 23, 2019, which had been amended on January 1, 2020. Pursuant to the Ostrander Amendment, Mr. Ostrander's base salary was increased from $226,600 to $275,000 and his bonus target was increased to 30% of his base salary. Mr. Ostrander was also eligible for other benefits consistent with those received by our other executives.

On December 15, 2021, we entered into a four-year employment agreement, effective as of January 1, 2022, with William Ostrander (the "Ostrander Employment Agreement"), to continue to serve as our Chief Financial Officer and Corporate Secretary. The Ostrander Employment Agreement replaced the Offer Letter entered into by us with Mr. Ostrander, dated September 23, 2019, as amended on January 1, 2020 and January 4, 2021. Pursuant to the Ostrander Employment Agreement, Mr. Ostrander is entitled to an annual base salary of $350,000 and will be eligible for discretionary performance bonus payments of thirty-five percent (35%) of his annual base salary. If Mr. Ostrander's employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided, however, that if his employment is terminated by us without Just Cause (as defined in the Ostrander Employment Agreement) then in addition to paying the Accrued Obligations, (i) we shall continue to pay his then current base salary for a period of six (6) months; and (ii) the vesting on all unvested options shall be accelerated so that all options shall become fully vested. If his employment is terminated within one year of a Change of Control (as defined in the 2018 Stock Incentive Plan), he will be paid his then current base salary for a period of six (6) months.

2021 Director Compensation

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2021 regarding the compensation of our directors who at December 31, 2021 were not also named executive officers.

Name and Principal Position	Fees Earned or Paid in Cash	Option Awards	Stock Awards	Totals
John Monahan, Ph.D. (1)	$ 86,500	$ 381,434	$ —	$ 467,934
John K. A. Prendergast, Ph.D. (2)	$ 286,000	$ 407,505	$ 784,002	$ 1,477,507
Edward B. Smith, III (1)	$ 97,500	$ 381,434	$ —	$ 478,934

1) The stock options are computed in accordance with FASB ASC 718 and reflect the value of an option to (i) purchase 65,217 shares of common stock granted on January 4, 2021 to Dr. Monahan and Mr. Smith that vest 100% on grant date, (ii) 32,467 shares of common stock granted on December 30, 2021 to Dr. Monahan and Mr. Smith that vest pro-rata monthly over 12 months, and (iii)129,820 shares of common stock granted on December 30, 2021 to Mr. Prendergast that vest pro-rata monthly over 12 months, subject to continued service as a board member through such date. The fair value of the options was calculated in accordance with FASB ASC 718, and the assumptions used are described in Note 11 to the Company's audited consolidated financial statements for the years ended December 31, 2021 and 2020. Each of the option grants is subject to forfeiture if an amendment to the 2018 Stock Incentive Plan to increase the number of shares of common stock available for grant is not approved by our stockholders.

2) Restricted stock awards are computed in accordance with FASB ASC 718 and reflect the aggregate grant date fair value of 138,272 shares granted on January 4, 2021 that vest 100% vest on grant date subject to continued service as a board member through such date. The fair value of the restricted stock is based on the closing stock price of an unrestricted share of the Company's common stock on the grant date. As of December 31, 2021, the following table sets forth the number of aggregate outstanding option awards held by each of our directors who were not also named executive officers:

Name	Aggregate Number of Option Awards	Aggregate Number of Stock Awards
John Monahan, Ph.D.	143,695	–
John K. A. Prendergast, Ph.D.	135,684	238,271
Edward B. Smith, III	143,695	–

Our Compensation Committee conducted an evaluation of the compensation of the members of our Board of Directors for 2021 with assistance from Meridian. Based on Meridian's review, 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. In January 2021 after consultation with Meridian, it was determined that directors who are not employees will receive an annual cash fee of $40,000 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.

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

The following table sets forth information, as of March 9, 2022, or as otherwise set forth below, with respect to the beneficial ownership of our common stock (i) all persons know to us to be the beneficial owners of more than 5% of the outstanding shares of our common stock, (ii) each of our directors and our executive officer named in the Summary Compensation Table, and (iii) all of our directors and our executive officer as a group. As of March 9, 2022, we had 25,649,824 shares of common stock outstanding.

Security Ownership of Management and Certain Beneficial Owners

Unless otherwise indicated the mailing address of each of the stockholders below is c/o Heat Biologics, Inc., 627 Davis Drive, Suite 400, Morrisville, North Carolina 27560. Except as otherwise indicated, and subject to applicable community property laws, except to the extent authority is shared by both spouses under applicable law, the Company believes the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Name of Beneficial Owner	Common Stock	Shares subject to Options (1)	Total Number of Shares Beneficially Owned	Percentage Ownership
Executive Officers & Directors				
Jeffrey Wolf (Chairman of the Board of Directors, Chief Executive Officer and President) (2)	1,094,045 (3)	645,615	1,739,660	6.6 %
William L. Ostrander (Chief Financial Officer and Secretary)	1,597	57,843	59,440	*
John K. A. Prendergast, Ph.D. (Director)	238,272 (4)	49,137	287,409	1.1 %
John Monahan, Ph.D. (Director)	73	119,907	119,980	*
Edward B. Smith, III (Director)	143	119,907	120,050	*
All Executive Officers and Directors, as a group (5 persons)	1,334,130	992,409	2,326,539	8.7 %

* less than 1%

(1) Represents shares subject to options that are currently vested and options that will vest and become exercisable within 60 days of March 9, 2022.

(2) Includes 11,025 shares of common stock held by Orion Holdings V, LLC and 10,231 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 equal to or in excess of $500 million for at least fifteen 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.

(3) Includes 814,144 unvested shares received pursuant to restricted stock awards granted in December 2019 and January 2020 that are subject to forfeiture.

(4) Includes 5,715 unvested shares received pursuant to restricted stock awards granted in January 2020 that are subject to forfeiture.

The following table sets forth information, as of March 9, 2022, or as otherwise set forth below, with respect to the beneficial ownership of our directors and named executive officers of the common stock of each of our subsidiaries set forth below and (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.

Name of Beneficial Owner	Pelican Therapeutics, Inc.(1) Common Stock Beneficially Owned	%	Skunkworx Bio, Inc.(2) Common Stock Beneficially Owned	%	Abacus Biotech, Inc. (2) Common Stock Beneficially Owned	%	Scorpion Biological Services, Inc. (2) Common Stock Beneficially Owned	%	Blackhawk Bio, Inc.(2) Common Stock Beneficially Owned	%
Jeffrey Wolf	178,829	3.1%	10,526	5.0%	10,526	5.0%	10,638	5.0%	10,526	5.0%
William Ostrander	—		—		—		2,127	1.0%	—	
John K. A. Prendergast, Ph.D.	—		—		—		—		—	
John Monahan, Ph.D.	2,605	*	—		—		—		—	
Edward B. Smith, III	15,148	*	—		—		—		—	
Total	196,582	3.4%	10,526	5.0%	10,526	5.0%	12,765	6.0%	10,526	5.0%

* less than 1%

(1) The shares of common stock of Pelican were issued to each individual prior Pelican becoming a subsidiary of our company.

(2) Consists of options issued in each applicable subsidiary pursuant to The Heat Biologics, Inc. 2021 Subsidiaries Stock Plan. Percent is the beneficial ownership percent for each individual in the applicable subsidiary.

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 Section 120 of the NYSE American Company Guide. For purposes of the Audit Committee Charter, "Related Party Transactions" shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404.

The following is a summary of transactions since January 1, 2020 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 entitled Part III, Item 10. "Directors, Executive Officers and Corporate Governance—2020 Director Compensation" and Part III, Item 11. "Executive Compensation:"

Compensation paid to our executive officers during 2020 and 2021 and equity awards granted to our executive officers and directors during 2020, 2021, 2022 and payments due to interests in Pelican, are disclosed under the sections of this Annual Report on Form 10-K entitled Part III, Item 10. "Directors, Executive Officers and Corporate Governance—2021 Director Compensation" and Part III, Item 11. "Executive Compensation" and Note 4 to the Company's audited consolidated financial statements for the years ended December 31, 2021 and 2020 "Acquisition of Pelican Therapeutics."

On December 20, 2021, we entered into the Merger Agreement with Merger Sub, Elusys and Fortis Advisors LLC pursuant to which, subject to certain conditions, we intend to acquire Elusys through the Merger. Elusys was formed in 1998 by Jeff Wolf, our President, Chief Executive Officer and Chairman of the Board of Directors, who is a director of Elusys and directly and through affiliated entities owns approximately 1.2% of the outstanding stock of Elusys, in the form of common stock, which is subordinate in terms of distributions to the Elusys preferred stock. However, pursuant to the terms governing the Elusys preferred stock, the preferred stockholders of Elusys will receive all of the initial $5 million of Merger Consideration and all of the net payments from the $31 million of revenues related to fulfillment of the existing SNS contract. While the amount of earn out payments, if any, to be made over the 12 year period following closing is very uncertain, it also presently seems likely that most if not all of such payments will also be paid to the preferred stockholders

of Elusys under the terms of such preferred stock. See" Business - Recent Developments" for a more complete description of the Merger Agreement.

Indemnification agreements

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

Independence of the Board of Directors

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

Item 14. ***Principal Accountant Fees and Services***

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2021 and 2020 by BDO USA, LLP.

	December 31, 2021	December 31, 2020
Audit Fees and Expenses (1)	$ 376,123	329,213

(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 for the fiscal years ended December 31, 2021 and 2020:

1. Report of Independent Registered Public Accounting Firm
2. Consolidated Balance Sheets as of December 31, 2021 and 2020
3. Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2021 and 2020
4. Consolidated Statements of Stockholders' Equity for the years ended December 31, 2021 and 2020
5. Consolidated Statements of Cash Flows for the years ended December 31, 2021 and 2020
6. Notes to Consolidated Financial Statements

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

(a)(3) The exhibits set forth in the accompanying exhibit index below are either filed as part of this report or are incorporated herein by reference:

EXHIBIT INDEX

Exhibit No.	Description
1.1	Amended and Restated At Market Issuance Sales Agreement, dated August 24, 2020, by and among Heat Biologics, Inc., B. Riley Securities, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 24, 2020 (File No. 001-35994))
1.2	Amendment No. 1, dated December 10, 2020, to the Amended and Restated At Market Issuance Sales Agreement, dated August 24, 2020, by and among Heat Biologics, Inc., B. Riley Securities, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3 filed with the SEC on December 10, 2020 (File No. 001-35994))
2.1	Merger Agreement, dated December 20, 2021, by and among Heat Biologics, Inc., Heat Acquisition Sub 1, Inc. and Elusys Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2021 (File No. 001-35994))
3.1	Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.5 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 (incorporated by reference to Exhibit 3.6 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365))
3.3	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 17, 2017 (File No. 001-35994))

Exhibit No.	Description
3.4	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 19, 2018 (File No. 001-35994))
3.5	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission March 23, 2018 (File No. 001 35994))
3.6	Amended and Restated Bylaws, dated October 17, 2019 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 18, 2019 (File No. 001-35994))
3.7	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8 K with the Securities and Exchange Commission on March 23, 2020 (File No. 001 35994))
3.8	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File No. 001 35994))
4.1#	2009 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 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 (incorporated by reference to Exhibit 4.2 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 (incorporated by reference to Exhibit 4.3 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 (incorporated by reference to Exhibit 4.4to 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 (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.6	Specimen Common Stock Certificate of Heat Biologics, Inc. (incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.7#	2014 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on June 13, 2014 (File No. 333-196763))
4.8#	Amended and Restated Heat Biologics, Inc. 2014 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 22, 2015))
4.9#	2017 Stock Incentive Plan (incorporated by reference as Exhibit 4.1 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on July 11, 2017 (File No. 333-219238))
4.10	Rights Agreement between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company dated March 11, 2018 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on March 12, 2018 (File No. 001-35994))
4.11#	2018 Stock Incentive Plan ((incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
4.12	Warrant Agency Agreement between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company dated May 2, 2018 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on May 7, 2018 (File No. 001-35994))
4.13	Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K with the Securities and Exchange Commission on May 7, 2018 (File No. 001-35994))
4.14	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on November 21, 2018 (File No. 001-35994))

Exhibit No.	Description
4.15	Amendment No. 1 to Rights Plan (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2019 (File No. 001-35994))
4.16	Amendment No. 2 to the Rights Agreement dated as of March 10, 2020 to the Rights Agreement dated March 11, 2018, as amended by Amendment No. 1 thereto, dated as of March 8, 2019, by and between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company, as rights agent (incorporated by reference to Exhibit 4.3 to the Form 8-A/A filed with the Securities and Exchange Commission on March 13, 2020 (File No. 001-35994))
4.17	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 21, 2020 (File No. 001-35994))
4.18*	Description of Securities of Heat Biologics, Inc.
4.19	Amendment No. 3 to the Rights Agreement dated as of March 8, 2021 to the Rights Agreement dated March 11, 2018, as amended by Amendment No. 1 thereto, dated as of March 8, 2019, and Amendment No. 2 thereto, dated as of March 10, 2020, by and between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company, as rights agent (incorporated by reference to Exhibit 4.1 to the Form 8-K filed with the Securities and Exchange Commission on March 12, 2021 (File No. 001-35994))
4.20	Heat Biologics, Inc. 2021 Subsidiaries Stock Incentive Plan (incorporated by reference as Exhibit B to the Heat Biologics, Inc. Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994))
4.21	Amendment No. 4 to the Rights Agreement dated as of March 8, 2021 to the Rights Agreement dated March 11, 2018, as amended by Amendment No. 1 thereto, dated as of March 8, 2019, Amendment No. 2 thereto, dated as of March 10, 2020, and Amendment No. 3 thereto dated as of March 8, 2021 by and between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company, as rights agent (incorporated by reference to Exhibit 4.5 to the Form 8-K filed with the Securities and Exchange Commission on March 11, 2022 (File No. 001-35994)
10.1**	License Agreement (97-14) between the University of Miami and its School of Medicine and Heat Biologics, Inc. effective July 11, 2008 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021 (File No. 001-35994))
10.2**	License Agreement (D-107) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021 (File No. 333-001-35994))
10.3**	License Agreement (SS114A) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011 (incorporated by reference to Exhibit 10.4 to the Current report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021 (File No. 001-35994))
10.4#	Employment Agreement with Jeffrey Wolf dated December 18, 2009 (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.5#	Amendment to Employment Agreement with Jeffrey Wolf dated as of January 1, 2011 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.6	Amendment to License Agreement (UM97-14) dated April 29, 2009 (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.7	Exclusive License between Heat Biologics, Inc. and the University of Michigan dated July 22, 2011 (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.8	Option Contract for Exclusive License between Heat Biologics, Inc. and the University of Miami dated April 1, 2013 (incorporated by reference to Exhibit 10.29 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.9#	Amendment to Employment Agreement, dated as of January 20, 2014, between the Company and Jeffrey Wolf (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K with the Securities and Exchange Commission on January 21, 2014 (File No. 001-35994))

Exhibit No.	Description
10.10#	Form of Incentive Stock Option Agreement under the 2014 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994))
10.11#	Form of Non-Statutory Stock Option Agreement under the 2014 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994))
10.12#	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated January 11, 2016 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994))
10.13#	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated April 1, 2016 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994))
10.14	Amendment to License Agreement (UM97-14) between the University of Miami and Heat Biologics, Inc. effective July 26, 2016 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994))
10.15	Form of Indemnification Agreement by and between Heat Biologics, Inc. and its directors and officers (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994))
10.16	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 (incorporated by reference to Exhibit 10.5 to the Current report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021 (File No. 001-35994))
10.17#	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated January 1, 2017 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994))
10.18#	Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994))
10.19	Stock Purchase Agreement by and among Heat Biologics, Inc., with Pelican Therapeutics, Inc. ("Pelican"), and certain stockholders in Pelican (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on March 8, 2017 (File No. 001-35994))
10.20	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 (incorporated by reference to Exhibit 10.67 to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2017 (File No. 001-35994))
10.21	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 (incorporated by reference to Exhibit 10.66 to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2017 (File No. 001-35994))
10.22*+	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)
10.23*+	License Agreement by and between University of Miami and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated December 12, 2010 (UMI176)
10.24*+	Amendment to License Agreement between Heat Biologics, Inc. and University of Miami (UM03-31, UM05-39) dated April 20, 2009
10.25*+	Second Amendment to License Agreement between Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) and University of Miami dated August 11, 2009 (UMC-131, UMC-139) (incorporated by reference to Exhibit 10.7 to the 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))
10.26*+	License Agreement by and between University of Miami and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated November 19, 2013 (UMI143 and UMN 106)
10.27*+	CPRIT Grant

Exhibit No.	Description
10.28*+	Assignment and Assumption Agreement between Heat Biologics, Inc. and Pelican Therapeutics, Inc.(f/k/a Heat Biologics II, Inc.) dated June 26, 2009 (UM131-31, UM139)
10.29#	Form of Incentive Stock Option Agreement under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.77 to the Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))
10.30#	Form of Non-Statutory Stock Option Agreement under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.78 to the Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))
10.31#	Form of Restricted Stock Unit Award Agreement under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.79 to the Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))
10.32#	Form of Incentive Stock Option Agreement under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.33#	Form of Non-Statutory Stock Option Agreement under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.34#	Form of Notice of Award under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.35#	Form of Restricted Stock Agreement under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.36#	Heat Biologics, Inc. Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2019 (File No. 001-35994))
10.37	Lease between Durham KTP Tech 7, LLC and Heat Biologics, Inc. dated April 17, 2019 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 18, 2019 (File No. 001-35994))
10.38#	Amendment No. 1 to the Heat Biologics, Inc. 2018 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 4, 2019 (File No. 001-35994))
10.39	Offer Letter by and between Heat Biologics, Inc. and William L. Ostrander, dated September 23, 2019 (incorporated by reference to Exhibit 10.2 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 18, 2019 (File No. 001-35994))
10.40#	Amendment to Employment Agreement between Heat Biologics, Inc. and Jeffrey Wolf, effective as of January 1, 2020 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.41#	Amendment to Offer Letter between Heat Biologics, Inc. and William Ostrander, effective as of January 1, 2020 (incorporated by reference to Exhibit 10.3 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.42#	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.4 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.43#	Amendment no. 2 to the Heat Biologics 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 filed with the Securities and Exchange Commission on March 12, 2020)
10.44	Form of Exchange Agreement (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on March 3, 2020 (File No. 001-35994))

Exhibit No.	Description
10.45+	Attachment F to CPRIT Contract (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 10, 2020)
10.46#	Amendment No. 3 to the Heat Biologics, Inc. 2018 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on July 27, 2020)
10.47	Amendment, dated December 7, 2020, to License Agreement (UMI-176) between the University of Miami and Heat Biologics, Inc. effective December 12, 2010 (incorporate by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File No. 001-35994))
10.48	Amendment, dated December 7, 2020, to License Agreement (UMSS-114) between the University of Miami and Heat Biologics, Inc. effective July 11, 2008 (incorporate by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File No. 001-35994))
10.49	Amendment, dated December 7, 2020, to License Agreement (D-107) between the University of Miami and Heat I, Inc. effective February 18, 2011 (incorporate by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File No. 001-35994))
10.50	Exclusive License Agreement between the University of Miami and Zolovax, Inc. dated as of December 31, 2020 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.51#	Amendment to Offer Letter between Heat Biologics, Inc. and William Ostrander, dated as of January 4, 2021 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.52#	Employment Agreement between Heat Biologics, Inc. and Jeffrey Wolf, dated as of January 4, 2021 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.53#	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.54#	Separation Agreement dated December 31, 2020 between Heat Biologics, Inc. And Jeff Hutchins (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.55	Lease between Durham Keystone Tech 7, LLC and Heat Biologics, Inc. dated June 21, 2021 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 23, 2021 (File No. 001-35994))
10.56#	Form of Stock Option Agreement for the Heat Biologics 2021 Subsidiaries Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994))
10.57#	Form of Restricted Stock Purchase Agreement for the Heat Biologics 2021 Subsidiaries Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994))
10.58#	Heat Biologics, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit A to the Definitive Proxy Statement on Schedule A filed with the Securities and Exchange Commission on August 3, 2021) (File No. 001-35994))
10.59	Lease between Merchants Ice II, LLC and Heat Biologics, Inc. dated June October 5, 2021 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 7, 2021 (File No. 001-35994))
10.60#	Form of Amended and Restated Restricted Stock Agreement (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 15, 2021(File No.001-35994)
10.61#	Employment Agreement effective as of January 1, 2022 by and between Heat Biologics, Inc. and William Ostrander (incorporated by reference to Exhibit 10.2 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 15, 2021(File No.001-35994)

Exhibit No.	Description
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) or15d 14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of William Ostrander, Principal Financial Officer, pursuant to Rule 13a 14(a) or15d 14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Jeffrey Wolf, Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of William Ostrander, Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document *
101.SCH	Inline XBRL Taxonomy Extension Schema Document *
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document *
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document *
104	Cover Page Interactive Data File (formatted in Inline XBRL in Exhibit 101)

* 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 to this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 11th day of March 2022.

HEAT BIOLOGICS, INC.

By: /s/ Jeffrey Wolf
Jeffrey Wolf
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)
Date: March 11, 2022

By: /s/ William L. Ostrander
William L. Ostrander
Chief Financial Officer, and Secretary
(Principal Financial and Principal Accounting Officer)
Date: March 11, 2022

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Jeffrey Wolf Jeffrey Wolf	Chief Executive Officer, President and Chairman of the Board (Principal Executive Officer)	March 11, 2022
/s/ William L. Ostrander William L. Ostrander	Chief Financial Officer, and Secretary (Principal Financial and Principal Accounting Officer)	March 11, 2022
/s/ John Monahan, Ph.D. John Monahan, Ph.D.	Director	March 11, 2022
/s/ John K.A. Prendergast, Ph.D. John K.A. Prendergast, Ph.D.	Director	March 11, 2022
/s/ Edward B. Smith, III Edward B. Smith, III	Director	March 11, 2022

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Heat Biologics, Inc. (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Contingent Consideration

As described in Notes 2 and 4 to the Company's consolidated financial statements, the Company has recorded a contingent consideration liability of approximately $3.3 million related to the acquisition of Pelican Therapeutics, Inc. on April 27, 2017. Contingent consideration is measured at fair value using a probability-weighted income approach utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, the estimated timing of milestone achievement, and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones.

We have identified the estimate of contingent consideration as a critical audit matter. Due to the Company's limited historical clinical trial experience, the inherent uncertainty involved in estimating the probabilities of success and time to milestones, and the complexity of the valuation methodology utilized by management, auditing the contingent consideration liability required increased auditor effort, including the use of valuation specialists.

The primary procedures we performed to address this critical audit matter included:

- Assessing management's estimated timing of milestone achievement and probabilities of success by corroborating with clinical development personnel knowledgeable of the current progression of the product candidate and performing a retrospective review over management's estimates from prior periods.
- Evaluating the reasonableness of inputs and assumptions used by management to determine the probabilities of success and timing of achievement of milestones by comparing them to external market and industry data.
- Utilizing professionals with specialized knowledge and experience in valuation to evaluate the valuation methodology applied by management, as well as assessing the appropriateness of the discount rate selected by management.

Impairment of Goodwill and In-process R&D

As described in Notes 2 and 7 to the Company's consolidated financial statements, the Company has recorded goodwill and in-process R&D ("IPR&D) in connection with the acquisition of Pelican Therapeutics, Inc. on April 27, 2017. The Company tests goodwill and in-process R&D for impairment each year as of April 1, or more frequently should a significant impairment indicator occur. During the fourth quarter of 2021, due to a sustained decline in the quoted market price of its common stock, the Company performed an interim impairment analysis using the income approach which resulted in the recognition of goodwill and IPR&D impairment expenses of approximately $1.5 million and $2.4 million, respectively.

We identified the valuation performed in connection with the impairment assessment of goodwill and IPR&D as a critical audit matter. The impairment assessment required significant judgments related to (i) forecasted financial information, including the estimation of future development costs, the probability of success in various phases of its development programs and potential post-launch cash flows, and (ii) estimate of risk-adjusted weighted average cost of capital. Due to the Company's limited historical clinical trial experience, the inherent uncertainty involved in estimating the future cash flows and the risk-adjusted weighted average cost of capital, and the complexity of the impairment methodology utilized by management, auditing the impairment analysis required increased auditor effort, including the use of valuation specialists.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the estimated future development costs by performing a retrospective review in comparison to previous management estimates,
- Comparing estimated probabilities of success, future development costs, and potential post-launch costs used by management to external market and industry data.
- Utilizing professionals with specialized knowledge and experience in valuation to evaluate the valuation methodology applied by management, and to test specific assumptions including the weighted average cost of capital.

/s/ BDO USA, LLP

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

Raleigh, North Carolina
March 11, 2022

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
Current Assets		
Cash and cash equivalents	$ 8,053,879	$ 10,931,890
Short-term investments	88,324,922	100,842,438
Accounts receivable	66,049	177,239
Prepaid expenses and other current assets	2,886,520	1,842,620
Total Current Assets	99,331,370	113,794,187
Property and Equipment, net	2,158,479	676,262
Other Assets		
In-process R&D	3,500,000	5,866,000
Goodwill	—	1,452,338
Grant receivable	1,318,359	—
Operating lease right-of-use asset	1,782,884	2,035,882
Finance lease right-of-use asset	470,700	247,194
Other assets	12,193,540	—
Deposits	205,901	122,779
Total Other Assets	19,471,384	9,724,193
Total Assets	$ 120,961,233	$ 124,194,642
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 922,782	$ 1,051,764
Deferred revenue, current portion	—	603,717
Operating lease liability, current portion	350,343	278,753
Finance lease liability, current portion	260,574	108,127
Accrued expenses and other liabilities	2,419,676	1,614,534
Contingent consideration, current portion	593,037	—
Contingent consideration, related party - current portion	174,333	—
Total Current Liabilities	4,720,745	3,656,895
Long Term Liabilities		
Other long-term liabilities	53,530	36,243
Derivative warrant liability	11,020	33,779
Deferred tax liability	215,937	361,911
Deferred revenue, net of current portion	35,000	237,500
Operating lease liability, net of current portion	1,060,856	1,301,636
Financing lease liability, net of current portion	255,429	160,240
Contingent consideration	1,990,118	2,250,844
Contingent consideration, related party	585,027	661,671
Total Liabilities	8,927,662	8,700,719
Commitments and Contingencies (Note 9 and 13)		
Stockholders' Equity		
Common stock, $.0002 par value; 250,000,000 and 250,000,000 shares authorized, 25,649,824 and 22,832,428 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	5,055	4,519
Additional paid-in capital	278,890,153	247,048,349
Accumulated deficit	(165,718,953)	(130,647,485)
Accumulated other comprehensive loss	(67,941)	(166,056)
Total Stockholders' Equity - Heat Biologics, Inc.	113,108,314	116,239,327
Non-Controlling Interest	(1,074,743)	(745,404)
Total Stockholders' Equity	112,033,571	115,493,923
Total Liabilities and Stockholders' Equity	$ 120,961,233	$ 124,194,642

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.
Consolidated Statements of Operations and Comprehensive Loss

	Year ended December 31,	
	2021	**2020**
Revenue:		
Grant and contract revenue	$ 2,112,806	$ 2,947,969
Operating expenses:		
Research and development	18,821,278	12,938,895
General and administrative	16,828,229	14,934,436
Goodwill impairment loss	1,452,338	—
Change in fair value of contingent consideration	430,000	1,199,000
Total operating expenses	37,531,845	29,072,331
Loss from operations	(35,419,039)	(26,124,362)
Change in fair value of warrant liability	22,758	(1,012,167)
Investor relations expense	—	(66,767)
Interest income	815,316	566,718
Other (expense) income, net	(965,816)	255,189
Total non-operating income (loss)	(127,742)	(257,027)
Net loss before income taxes	(35,546,781)	(26,381,389)
Income tax benefit (expense)	145,974	—
Net loss	(35,400,807)	(26,381,389)
Net loss - non-controlling interest	(329,339)	(331,652)
Net loss attributable to Heat Biologics, Inc.	$ (35,071,468)	$ (26,049,737)
Net loss per share, basic and diluted	$ (1.41)	$ (1.63)
Weighted-average common shares outstanding, basic and diluted	24,913,942	15,982,568
Comprehensive loss:		
Net loss	(35,400,807)	(26,381,389)
Unrealized gain (loss) on foreign currency translation	98,115	(154,806)
Total comprehensive loss	(35,302,692)	(26,536,195)
Comprehensive loss attributable to non-controlling interest	(329,339)	(331,652)
Comprehensive loss - Heat Biologics, Inc.	$ (34,973,353)	$ (26,204,543)

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.
Consolidated Statements of Stockholders' Equity

	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Non-Controlling Interest	Total Stockholders Equity
Balance at December 31, 2019	$ 965	$ 118,179,635	$ (104,597,748)	$ (11,250)	$ (413,752)	$ 13,157,850
January 2020 investment offering, net of underwriters discounts	572	4,105,577	—	—	—	4,106,149
ATM raise	2,635	117,370,860	—	—	—	117,373,495
Issuance of common stock from vesting of restricted stock awards	56	(56)	—	—	—	—
Stock issuance costs	—	(3,103,833)	—	—	—	(3,103,833)
Stock based compensation	—	6,377,857	—	—	—	6,377,857
Exercise of warrants	227	3,442,095	—	—	—	3,442,322
Exchange of warrants	64	773,266	—	—	—	773,330
Payment of cash in lieu of fractional shares	—	(97,052)	—	—	—	(97,052)
Other comprehensive loss	—	—	—	(154,806)	—	(154,806)
Net loss	—	—	(26,049,737)	—	(331,652)	(26,381,389)
Balance at December 31, 2020	4,519	247,048,349	(130,647,485)	(166,056)	(745,404)	115,493,923
ATM raise	420	26,303,862	—	—	—	26,304,282
Issuance of common stock from vesting of restricted stock awards	110	(110)	—	—	—	—
Stock issuance costs	—	(658,184)	—	—	—	(658,184)
Stock based compensation	—	6,168,981	—	—	—	6,168,981
Cancellation and payout of fractional shares	(3)	3	—	—	—	—
Issuance of restricted stock	3	(3)				
Exercise of options	6	27,255	—	—	—	27,261
Other comprehensive loss	—	—	—	98,115	—	98,115
Net loss	—	—	(35,071,468)	—	(329,339)	(35,400,807)
Balance at December 31, 2021	$ 5,055	$ 278,890,153	$ (165,718,953)	$ (67,941)	$ (1,074,743)	$ 112,033,571

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS, INC.
Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2021	**2020**
Cash Flows from Operating Activities		
Net loss	$ (35,400,807)	$ (26,381,389)
Adjustments to reconcile net loss to net cash used in operating activities:		
Goodwill impairment loss	1,452,338	—
In-process R&D impairment loss	2,366,000	—
Depreciation and amortization	607,667	333,152
Noncash lease expense	83,809	95,600
Noncash interest expense	21,970	17,972
Noncash investor relations expense	—	66,767
Stock-based compensation	6,168,981	6,377,857
Change in fair value of common stock warrants	(22,758)	1,012,167
Change in fair value of contingent consideration	430,000	1,199,000
Unrealized loss (gain) on investments	842,538	(44,871)
Increase (decrease) in cash arising from changes in assets and liabilities:		
Accounts receivable	110,111	(140,559)
Prepaid expenses and other current assets	(1,060,915)	(1,419,395)
Grant receivable	(1,318,359)	—
Other assets	(12,193,540)	—
Accounts payable	(126,937)	(452,778)
Accrued expenses and other liabilities	929,023	(223,882)
Deferred revenue	(806,217)	(2,769,101)
Deferred tax liability	(145,974)	—
Other long-term liabilities	17,286	36,243
Deposits	(83,122)	271,858
Net Cash Used in Operating Activities	(38,128,906)	(22,021,359)
Cash Flows from Investing Activities		
Purchase of short-term investments	(66,960,279)	(105,925,802)
Sale of short-term investments	78,635,257	10,842,157
Purchase of property and equipment	(1,904,713)	(337,972)
Proceeds from disposal of property and equipment	—	2,168
Net Cash Provided By (Used in) Investing Activities	9,770,265	(95,419,449)
Cash Flows from Financing Activities		
Proceeds from public offering of common stock and warrants	—	6,600,971
Proceeds from the issuance of common stock	26,304,282	117,373,495
Proceeds from exercise of stock options	27,261	—
Proceeds from the exercise of warrants	—	675,675
Stock issuance costs	(658,184)	(3,103,833)
Cash paid for fractional shares in connection with reverse stock split	—	(97,052)
Payment of contingent consideration	—	(2,005,000)
Proceeds from PPP loan	—	702,000
Repayment of PPP loan	—	(702,000)
Repayments on principal of finance lease	(183,010)	(115,199)
Net Cash Provided by Financing Activities	25,490,349	119,329,057
Effect of exchange rate changes on cash and cash equivalents	(9,719)	3,754
Net Change in Cash and Cash Equivalents	(2,878,011)	1,892,003
Cash and Cash Equivalents – Beginning of Period	10,931,890	9,039,887
Cash and Cash Equivalents – End of Period	$ 8,053,879	$ 10,931,890
Supplemental Disclosure for Cash Flow Information:		
Right-of-use assets obtained on operating lease commencements	$ 88,596	$ 75,244
Right-of-use assets obtained on operating lease modifications	$ 37,767	$ —
Right-of-use assets obtained on financing lease commencements	$ 408,677	$ 173,822
Supplemental disclosure of non-cash investing and financing activities:		
Allocation of proceeds from public offering to warrant liabilities	$ —	$ 2,494,823
Cashless exercise of warrants classified as liabilities	$ —	$ 2,766,647
Cashless exchange of warrants classified as liabilities	$ —	$ 773,330

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Heat Biologics is a biopharmaceutical company primarily engaged in the development of immune therapies and vaccines. Our gp96 platform is designed to activate the immune system. This platform has broad applications in cancer and infectious disease. The Company platform leverages gp96's role as a natural molecular warning system that presents antigens to the immune system. HS-110 (viagenpumatucel-L) is the Company's first allogeneic ("off-the-shelf") cell line biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's T-cells to destroy cancer. HS-130 is an allogeneic cell line engineered to express the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T-cells, with the potential to augment antigen-specific CD4+ T-cell and CD8+ T-cell responses. We have initiated development of a new COVID-19 vaccine program under our Zolovax, Inc. subsidiary that utilizes our gp96 platform to secrete SARS-CoV-2 antigens. The Company's subsidiary Pelican Therapeutics, Inc. ("Pelican"), is developing PTX-35, a novel T-cell co-stimulator agonist antibody targeting DR3/TNFRSF25 for systemic administration. The Company is also designing and building a cGMP facility in San Antonio, Texas for bioanalytics, process development, and manufacturing activities via its subsidiary Scorpion Biological Services, Inc.

These programs are designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. The Company has completed recruiting patients in its Phase 2 HS-110 non-small cell lung cancer (NSCLC) trial, dosed twelve patients in our Phase 1 clinical trial of HS-130 and dosed five patients in our Phase 1 clinical trial of PTX-35. The Company is also providing pre-clinical, CMC development, and administrative support for these operations; while constantly focusing on protecting and expanding our intellectual property in areas of strategic interest. As the Company advances its clinical programs, it is in close contact with the CROs and clinical sites and are assessing the impact of COVID-19 on the studies and current timelines and costs.

On December 20, 2021, we entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with our wholly owned subsidiary ("Merger Sub"), Elusys Therapeutics, Inc., a Delaware corporation ("Elusys") and Fortis Advisors LLC, pursuant to which, subject to certain conditions, we will acquire Elusys through the merger (the "Merger") of Merger Sub with Elusys. Following the closing of the Merger, Elusys will become a wholly owned subsidiary. Elusys is a company focused on the commercialization of ANTHIM® (obiltoxaximab), which is a monoclonal antibody antitoxin for the "Category A" biological warfare and bioterrorism threat anthrax designed to combat a potential anthrax attack. As of December 31, 2021, the merger has not been consummated.

Unless otherwise noted, all share and per share data referenced in the consolidated financial statements and the notes thereto have been retroactively adjusted to reflect the one-for-seven reverse stock split effective December 11, 2020. As a result of the reverse stock split, amounts within the consolidated balance sheets were reclassified between common stock and additional paid-in capital.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Heat Biologics, Inc. , and its subsidiaries ("the Company"), Pelican Therapeutics, Inc. ("Pelican"), 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., Skunkworx Bio, Inc. (formerly known as Delphi Therapeutics, Inc.), Scorpion Biological Services, Inc. ("Scorpion") (formerly Scorpion Biosciences, Inc), Blackhawk Bio, Inc., Abacus Biotech, Inc., and Heat Acquisition Sub 1, Inc., an entity formed to merge into Elusys upon consummation of the Merger. 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. The December 31, 2021 and 2020 year-end financials include 85% controlling interest in Pelican. Heat accounts for its less than 100% interest in the consolidated financial

statements in accordance with U.S. GAAP. Accordingly, the Company presents non-controlling interest as a component of stockholders' equity on its consolidated balance sheets and reports non-controlling interest net loss under the heading "net loss – non-controlling interest" in the consolidated statements of operations and comprehensive loss.

Liquidity and Capital Resources

The Company has an accumulated deficit of $165.7 million as of December 31, 2021 and a net loss of approximately $35.4 million for the year ended December 31, 2021 and has not generated significant revenue or positive cash flows from operations. The Company expects to incur significant expenses and continued losses from operations for the foreseeable future. The Company expects its expenses to increase in connection with its ongoing activities, particularly as the Company continues its research and development and advances its clinical trials of, and seeks marketing approval for, its product candidates and continues construction of its cGMP manufacturing facility and purchases equipment for the facility. In addition, if the Company obtains marketing approval for any of its product candidates, the Company expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, the Company will need to obtain substantial additional funding in connection with its continuing operations. Adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts. To meet its capital needs, the Company intends to continue to consider multiple alternatives, including, but not limited to, additional equity financings such as sales of its common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. On April 23, 2020, the Company filed a shelf registration statement on Form S-3 (the "Registration Statement"). Pursuant to the Registration Statement, the Company may offer and sell securities having an aggregate public offering price of up to $150 million. In connection with the filing of the Registration Statement, the Company also entered into an amendment to its sales agreement ("Common Stock Sales Agreement") with B. Riley FBR, as sales agent, pursuant to which the Company may issue and sell shares of its common stock under an at-the-market (the "ATM") offering program. On August 24, 2020, the Company amended and restated the Common Stock Sales Agreement (the "Amended and Restated Common Stock Sales Agreement") to include Cantor Fitzgerald & Co. ("Cantor") as an additional sales agent for the ATM. Pursuant to the ATM, the Company will pay B. Riley FBR or Cantor (each a "Designated agent" and collectively, the "Agents"), a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. As of December 31, 2021, the Company had approximately $96.4 million in cash and cash equivalents and short-term investments, which it believes is sufficient to fund its operations for at least one year from the date these consolidated financial statements were issued. This is based on the Company's current estimates, and the Company could use its available capital resources sooner than it currently expects. The Company is continually evaluating various cost-saving measures considering its cash requirements in order to focus resources on its product candidates. The Company will need to generate significant revenues to achieve profitability, and it may never do so.

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

In March 2020, the World Health Organization declared COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, and any related adverse public health developments, has adversely affected workforces, economies, and financial markets globally, potentially leading to an economic downturn. It has also disrupted the normal operations of many businesses. With the global spread of the ongoing COVID-19 pandemic, the Company has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its business. The extent to which the COVID-19 pandemic impacts the Company's business, the clinical development of the Company's products, the business of the Company's suppliers and other commercial partners, the Company's corporate

development objectives and the value of and market for the Company's common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The Company's in human phase 1 trial of HS-130 was subject to an approximate 8 week enrollment pause in April and May 2020 due to lack of personal protection equipment ("PPE") at a clinical site. The site ceased all non-critical/non-essential patient procedures until PPE supplies were available. Enrollment resumed and no delays in overall development milestones are expected for HS-130.

With the global spread of the ongoing novel coronavirus ("COVID-19") pandemic, the Company has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its employees and business. While the Company is experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, to the extent the ongoing COVID-19 pandemic adversely affects the Company's business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties which the Company faces.

On April 23, 2020, Heat and Pelican received loan proceeds of $0.7 million from Regions Bank, N.A, pursuant to the Paycheck Protection Program, or the PPP Loan, under the CARES Act, administered by the U.S. Small Business Administration. On April 28, 2020, the Company returned all $0.7 million in proceeds from the PPP Loan.

The Company relies on third-party manufacturers to purchase from their third-party vendors the materials necessary to produce product candidates and manufacture product candidates for clinical studies. The Company also depends on third-party suppliers for key materials and services used in research and development, as well as manufacturing processes, and are subject to certain risks related to the loss of these third-party suppliers or their inability to supply adequate materials and services. The Company does not control the manufacturing processes of the contract development and manufacturing organizations, or CDMOs, with whom it contracts and is dependent on these third parties for the production of its therapeutic candidates in accordance with relevant regulations (such as current Good Manufacturing Practices, or cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. In addition, the Company is dependent upon third-party suppliers for the materials needed to construct its cGMP facility as well as the equipment that will be needed to run the facility.

Use of Estimates

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

Immaterial Revision

During the course of preparing the Company's consolidated financial statements as of and for the year ended December 31 2021, the Company completed an Internal Revenue Code Section 382 and 383 analysis of its historical net operating loss and tax credit carryforward amounts. As a result, a portion of the prior year net operating loss and tax credit carryforwards were limited and incorrectly presented in the deferred tax table within Note 12. See Note 12—Income Taxes, for further details.

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. All of the Company's total consolidated assets are located within

the U.S. as of December 31, 2021 and 2020. For the years ended December 31, 2021 and 2020, 100%, of revenue was generated in the United States.

Cash and Cash Equivalents

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.

Short-term Investments

The Company's short-term investments consist of equity securities and are carried at fair value. Unrealized gains and losses on securities are reported in the consolidated statement of operations and comprehensive loss. The Company classifies marketable equity investments available to fund current operations as current assets on its consolidated balance sheets.

Derivative Financial Instruments

The Company has issued common stock warrants in connection with the execution of certain equity financings. The fair value of the warrants, which were deemed to be derivative instruments, was recorded as a derivative liability under the provisions of ASC Topic 815 Derivatives and Hedging ("ASC 815") because they are not considered indexed to the Company's own stock. Subsequently, the liability is adjusted to fair value as of the end of each reporting period and the changes in fair value of derivative liabilities are recorded in the consolidated statements of operations and comprehensive loss under the caption "Change in fair value of warrant liability."

The fair value of the warrants, including the warrants issued in connection with the January 2020 common stock offering and recorded as liability, was determined using the Monte Carlo simulation model, deemed to be an appropriate model due to the terms of the warrants issued.

The fair value of warrants was affected by changes in inputs to the Monte Carlo simulation model including the Company's stock price, expected stock price volatility, the remaining term, and the risk-free interest rate. At December 31, 2021, the fair value of such warrants was $11,020, which is classified as a long-term derivative warrant liability on the Company's consolidated balance sheets. At December 31, 2020, the fair value of warrants was $33,779.

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, 2021, and 2020, cash amounts in excess of $250,000 were not fully insured. The uninsured cash balance as of December 31, 2021 was $7,500,658. The Company does not believe it is exposed to significant credit risk on cash and cash equivalents.

Property and Equipment

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

Leases

The Company leases office space and certain equipment under non-cancelable lease agreements. The Company applies the accounting guidance in ASC 842, *Leases.* As such, the Company assesses all arrangements, that convey the right to control the use of property, plant and equipment, at inception, to determine if it is, or contains, a lease based on the unique facts and circumstances present in that arrangement. For those leases identified, the Company determines the lease

classification, recognition, and measurement at the lease commencement date. For arrangements that contain a lease the Company: (i) identifies lease and non-lease components; (ii) determines the consideration in the contract; (iii) determines whether the lease is an operating or financing lease; and (iv) recognizes lease Right of Use ("ROU") assets and corresponding lease liabilities. Lease liabilities are recorded based on the present value of lease payments over the expected lease term. The corresponding ROU asset is measured from the initial lease liability, adjusted by (i) accrued or prepaid rents; (ii) remaining unamortized initial direct costs and lease incentives; and (iii) any impairments of the ROU asset.

Fixed lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed are expensed as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within the accompanying consolidated statements of operations and comprehensive loss.

The interest rate implicit in the Company's lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Other Assets

In October 2021, Scorpion entered into a lease agreement with Merchants Ice II, LLC, to lease a20,144 square foot facility in San Antonio, TX for general office, laboratory, research, analytical, and/or biomanufacturing purposes. Merchants Ice II, LLC is a nonprofit entity investing in the building with the intention to encourage development of emerging technologies. As a result, investments made to the building could generate tax incentives under the New Market Tax Credit ("NMTC") program. Scorpion agreed that all investments and expenditures qualifying under the NMTC (i.e., certain equipment and building improvements) would be purchased by the Merchants Ice II, LLC to generate the largest possible tax incentive and Scorpion would reimburse Merchant Ice, LLC for these payments. To date, Scorpion has reimbursed Merchant Ice, LLC $12.2 million which is shown in "Other assets" on the consolidated balance sheets. Upon lease commencement, these assets will be classified as a right-of-use asset.

Net Loss per Share

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

Fair Value of Financial Instruments

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.

As of December 31, 2021, and December 31, 2020, the fair values of cash and cash equivalents, accounts payable, and accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. The Company's short-term investments consist of Level I securities which are comprised of highly liquid money market funds. The estimated fair value of the short-term investments was based on quoted market prices. There were no transfers between fair value hierarchy levels during the years ended December 31, 2021 or 2020.

In January 2020, the Company issued warrants in connection with the public offering of common stock (the "January 2020 Warrants"). Pursuant to the terms of these warrants, the warrants were not considered indexed to the Company's own stock and therefore are required to be measured at fair value and reported as a liability in the consolidated balance sheets. Additionally, upon the closing of the January 2020 offering, 479,595 outstanding warrants were evaluated whether they were modified for accounting purpose and were determined that they were required to be classified as a liability. The fair value of the warrant liability is based on the Monte Carlo methodology. The Company is required to revalue the warrants at each reporting date with any changes in fair value recorded on our consolidated statement of operations and comprehensive loss. The valuation of the warrants is classified under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. In order to calculate the fair value of the warrants, certain assumptions were made, including the selling price or fair market value of the underlying common stock, risk-free interest rate, volatility, and remaining life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimated a volatility factor utilizing its own data. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity.

The Monte Carlo simulation was used to value the liability-classified warrants, including the warrants reclassified from equity to liability. The following weighted average assumptions were used:

	January 21, 2020
Current stock price	$ 2.31
Estimated volatility of future stock price	124 %
Risk free interest rate	1.53 %
Contractual term	3.7 years

During the year ended December 31, 2020,470,238 warrants were exchanged for 319,756 shares of common stock. During the year ended December 31, 2021, no warrants were exchanged for shares of common stock. As of December 31, 2021 and 2020, there were a total of 9,357 warrants outstanding that were reported as a liability on the consolidated balance sheet.

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

	As of December 31, 2021			
Description	Total	Level 1	Level 2	Level 3
Assets:				
Short-term investments	$ 88,324,922	$ 88,324,922	—	—
Liabilities:				
Contingent consideration	$ 3,342,515	—	—	$ 3,342,515
Warrant liability	$ 11,020	—	—	$ 11,020

	As of December 31, 2020			
Description	Total	Level 1	Level 2	Level 3
Assets:				

Short-term investments	$ 100,842,438	$ 100,842,438	—	—
Liabilities:				
Contingent consideration	$ 2,912,515	—	—	$ 2,912,515
Warrant liability	$ 33,779	—	—	$ 33,779

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, 2021 and 2020:

	Contingent Consideration	Warrant Liability
Balance at December 31, 2019	$ 3,718,515	$ —
Fair value at issuance	—	2,494,823
Reclassification of warrants from equity to liability due to modification	—	869,078
Reclassification of warrant liability to equity upon cashless exercise of warrants	—	(2,766,647)
Reclassification of warrant liability to equity upon exchange of warrants	—	(1,575,642)
Payout of contingent consideration	(2,005,000)	—
Change in fair value	1,199,000	1,012,167
Balance at December 31, 2020	$ 2,912,515	$ 33,779
Change in fair value	430,000	(22,758)
Balance at December 31, 2021	$ 3,342,515	$ 11,020

The change in the fair value of the contingent consideration of $430,000 and $1,199,000 for the years ended December 31, 2021 and 2020, respectively, was primarily due to the effect of the change in discount rate, probability of achieving milestones, and passage of time on the fair value measurement. Adjustments associated with the change in fair value of contingent consideration are included in the Company's consolidated statement of operations and comprehensive loss.

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, 2021 and 2020:

	As of December 31, 2021		
	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent Consideration	Probability weighted income approach	Milestone dates	2022-2031
		Discount rate	7.51%
		Probability of occurrence	4.9% to 75%

	As of December 31, 2020		
	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent Consideration	Probability weighted income approach	Milestone dates	2022-2030
		Discount rate	7.66%
		Probability of occurrence	2.7% to 68%

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

The following table presents quantitative information about the inputs used in the valuation for the Company's fair value measurement of the warrant liability classified as Level 3 as of December 31, 2021:

	December 31, 2021	December 31, 2020
Current stock price	$ 3.04	$ 5.36
Estimated volatility of future stock price	133.13 %	141.28 %
Risk free interest rate	0.55 %	0.17 %
Contractual term	1.90 years	2.90 years

The Company measures certain non-financial assets on a non-recurring basis, including goodwill and in-process R&D. As a result of those measurements, during the year ended December 31, 2021, goodwill with a total carrying value of $1.5 million was written down and an impairment charge of $1.5 million was recorded. During the same period, in-process R&D with a total carrying value of $5.9 million was written down to its estimated fair value of $3.5 million and an impairment charge of $2.4 million was recorded in research and development expense. This analysis requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital.

The fair value of our reporting unit was determined using an income approach that utilizes a discounted cash flow model. The discounted cash flow models are dependent upon our estimates of future cash flows and other factors. Our estimates of future cash flows are based on a comprehensive product by product forecast over a period which covers Phase 1 to approval and 15 years of commercialized revenue and involve assumptions concerning (i) future operating performance, including research and development costs through approval of the drug, the future addressable market, future sales, long-term growth rates, operating margins, allocation and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions, all which may differ from actual future cash flows.

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes and represent our best estimate of the future results of our operations as of a point in time. These estimates are subject to many assumptions, such as the economic environments in which we operate, demand for the products and competitor actions. Estimated future cash flows are discounted to present value using a market participant, weighted average cost of capital, which considers the risk inherent in the probability adjusted future cash flows from each product. The financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and our market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions could increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of related goodwill impairments, if any.

Income Tax

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

In accordance with FASB ASC 740, Accounting for Income Taxes, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2021 and 2020, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the

accompanying consolidated statements of operations. As of December 31, 2021 and 2020, the Company had no such accruals.

Stock-Based Compensation

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

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, and expected term. The expected volatility rates are estimated based on average historical stock price volatility of its own data plus an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms. The expected term for the years ended December 31, 2021 and 2020 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. We account for forfeitures as they occur. The Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards.

Net Loss Attributable to Non-controlling Interests

Net loss attributable to non-controlling interests is the result of the Company's consolidation of subsidiaries of which it does not own 100%. In October 2018, the Company entered into an agreement with the University of Miami ("UM") whereby UM exchanged its shares of stock in the Company's subsidiaries, Heat I, Inc. and Pelican, a related party prior to acquisition, for 35,000 shares of the Company's common stock. The stock exchange resulted in the Company owning 100% of Heat I, Inc. and increasing its controlling ownership in Pelican from 80% to 85%. The Company's net loss attributable to non-controlling interests relates to the15% ownership of Pelican that Heat does not own as of December 31, 2021 and 2020.

Grants Receivable and Revenue Recognition

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

The CPRIT grant covers the periods from June 1, 2017 through May 31, 2022, for a total grant award of up to $15.2 million. CPRIT advances grant funds upon request by the Company consistent with the agreed upon amounts and schedules as provided in the contract. The first tranche of funding of $1.8 million was received in May 2017, and a second tranche of funding of $6.5 million was received in October 2017, and the third tranche of funding of $5.4 million was received in December 2019. The remaining $1.5 million will be awarded, on a reimbursement basis, after we have fulfilled every requirement of the grant and the grant has been approved to be finalized. Funds received are reflected in deferred revenue as a liability until revenue is earned. When grant funds are received after costs have been incurred, the Company records revenue and a corresponding grants receivable. Grant revenue is recognized when qualifying costs are incurred. Through December 31, 2021, $13.7 million of grant funding received to date has been recognized as revenue. As of December 31, 2021, we had a grant receivable balance of $1.3 million for CPRIT proceeds not yet received but for which the costs had been incurred or the conditions of the award had been met.

On January 7, 2020, the Company was awarded a grant of up to $224,713 from the NIH. The NIH grant provides funding for continued development of the Company's technologies for PTX-35. The grant funds will be made available by the NIH to the Company as allowable expenses are incurred. For the years ended December 31, 2020 and 2021, the Company incurred $0.1 million of allowable expenses under the NIH grant and recognized a corresponding amount of grant revenues. For the year ended December 31, 2021, there was no deferred revenue related to the grant that was recognized.

Business Combinations

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

Goodwill and In-Process Research and Development

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

IPR&D, assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D assets represent the fair value assigned to technologies that the Company acquires, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval and the ability to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value. See Note 7 regarding impairment at December 31, 2021.

Deferred Revenue

Deferred revenue is comprised of proceeds of grant funds 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 provided 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. The Economic Development Grant funds were recognized as revenue upon the achievement of the performance criteria and determination that the cash is no longer refundable to the State of Texas. On November 12, 2021, we mutually agreed with the City of San Antonio to terminate the agreement.

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 and comprehensive loss. Contingent consideration is measured at fair value using a probability-weighted income approach a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, the estimated timing of milestone achievement, and an estimated discount rate associated with the risks of the expected cash flows attributable to the various 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 reassesses the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long term liabilities in the consolidated balance sheets (see Note 4).

Research and Development

Research and development costs associated with developmental products not yet approved by the FDA as well as costs associated with bringing developmental products into advanced phase clinical trials are expensed 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, as well any in-process R&D impairment.

Impact of Recently Issued Accounting Standards:

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses which requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. This standard is effective for fiscal years beginning after December 15, 2022 and the Company is currently evaluating the expected impact of this standard but does not expect it to have a material impact on its consolidated financial statements upon adoption.

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This ASU simplifies the accounting for convertible instruments. This ASU also requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. The ASU is effective for annual periods beginning after December 15, 2021 with early adoption permitted. The Company is currently evaluating the impact this standard will have on our consolidated financial statements.

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

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

Short-term investments consist of equity securities with a maturity of greater than three months when acquired. The Company holds its securities at fair value as of December 31, 2021 and 2020. Unrealized gains and losses on securities of $1.0 million and $0.2 million, respectively, are reported in the consolidated statement of operations and comprehensive loss as Other expense (income), net for the years ended December 31, 2021 and 2020. Short-term investments at December 31, 2021 and 2020 consisted of mutual funds with fair values of $88.3 million and $100.8 million, respectively.

4. ***Acquisition of Pelican Therapeutics, Inc.***

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

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

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

The probability weighted fair value of these future milestone payments is reflected in the contingent consideration account under current liabilities with the non-current portion under long term liabilities on the balance sheet. The estimated fair value of the contingent consideration was determined using a probability-weighted income approach. The Company estimates the fair value of the contingent consideration on a quarterly basis. At the time of the Pelican acquisition, the Company's CEO and certain affiliated entities as well as two of the Company's directors and certain affiliated entities directly or indirectly owned shares of Pelican common stock purchased by the Company. As a result, approximately 22.7% of any such milestone payments will be paid to certain directors of the Company which is presented separately on the balance sheet as contingent consideration, related parties. On June 22, 2020, the Company achieved the first milestone, and paid $2.0 million during the year ended December 31, 2020, when it dosed the first patient in the first Phase 1 clinical trial of PTX-35.

Goodwill was calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill resulting from this acquisition related largely to synergies expected from combining the operations. The goodwill is not deductible for income tax purposes. In-process research and development assets are treated as indefinite-lived until the completion or abandonment of the associated research and development ("R&D") program, at which time the appropriate useful lives will be determined.

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

5. Prepaid Expenses and Other Current Assets

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

	December 31, 2021	December 31, 2020
Prepaid manufacturing expense	$ 563,280	$ 316,411
Prepaid insurance	704,650	612,293
Prepaid preclinical and clinical expenses	1,158,560	690,543
Other prepaid expenses and current assets	460,030	223,373
	$ 2,886,520	$ 1,842,620

6. Property and Equipment

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

Property and equipment consisted of the following at:

	December 31, 2021	December 31, 2020
Lab equipment	$ 3,178,855	$ 1,607,238
Computers	85,071	71,058
Furniture and fixtures	66,106	64,523
Leasehold improvements	22,563	22,563
Construction-in-process	309,620	—
Total	3,662,215	1,765,382
Accumulated depreciation	(1,503,736)	(1,089,120)
Property and equipment, net	$ 2,158,479	$ 676,262

Depreciation expense totaled $422,496 and $218,951 for the years ended December 31, 2021 and 2020, respectively.

7. Goodwill and In-process R&D

Goodwill of $2.2 million and in-process R&D of $5.9 million were recorded in connection with the acquisition of Pelican, as described in Note 4 and have been allocated to the Pelican reporting unit. For goodwill, accumulated impairment amounted to $2.2 million and $0.7 million as of December 31, 2021 and 2020, respectively. For in-process R&D, accumulated impairment amounted to $2.4 million and $0.0 million as of December 31, 2021 and 2020, respectively. The Company performs an annual impairment test at the reporting unit level as of April 1st of each fiscal year. As of April 1, 2021, the Company qualitatively assessed whether it is more likely than not that the respective fair value of the Company's Reporting Units (Heat, Pelican, and Scorpion) are less than its carrying amount, including goodwill. Based on that assessment, the Company determined that this condition did not exist. However, during the fourth quarter 2021, the Company experienced a sustained decline in the quoted market price of the Company's common stock and as a result the Company determined that as of December 31, 2021 it was more likely than not that the carrying value of these acquired intangibles exceeded their estimated fair value. Accordingly, the Company performed an interim impairment analysis as of that date using the income approach. This analysis required significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-

launch cash flows and a risk-adjusted weighted average cost of capital. Pursuant to ASU 2017-04, the Company recorded a goodwill impairment charge for the excess of the reporting unit's carrying value over its fair value. During the year ended December 31, 2021, goodwill with a total carrying value of $1.5 million was written down and an impairment charge of $1.5 million was recorded. During the same period, in-process R&D with a total carrying value of $5.9 million was written down to its estimated fair value of $3.5 million and an impairment charge of $2.4 million was recorded.

The following table provides the Company's goodwill as of December 31, 2021 and 2020. There was no goodwill impairment during the year ended December 31, 2020.

	Goodwill
Balance at December 31, 2020	$ 1,452,338
Goodwill impairment loss	(1,452,338)
Balance at December 31, 2021	$ —

The following table provides the Company's in-process R&D as of December 31, 2021. There was no change in in-process R&D during the year ended December 31, 2020.

	In-process R&D
Balance at December 31, 2020	$ 5,866,000
In-process R&D impairment loss	(2,366,000)
Balance at December 31, 2021	$ 3,500,000

8. Accrued Expenses

Accrued expenses consist of the following at:

	December 31, 2021	December 31, 2020
Accrued preclinical and clinical trial expenses	$ 955,013	$ 628,000
Accrued manufacturing expenses	179,173	175,089
Compensation and related benefits	459,178	209,600
Accrued franchise tax	195,000	172,500
Other expenses	631,312	429,345
	$ 2,419,676	$ 1,614,534

9. License Agreements

- *University of Miami*

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

  - The Company agreed to make minimum royalty payments of $10,000 for three years beginning in 2010 that are due on the anniversary date of the agreement for License Agreement 97-14. Beginning in 2013, and thereafter for the life of the agreement, the minimum royalty payment shall be $20,000 due on the same date. In July 2016, the Company and UM entered into an amendment which replaced the milestone payment of

$250,000 by approval of a BLA for the lung cancer vaccine with a payment of $500,000 upon approval of an NDA for a lung cancer vaccine covered by Patent Rights.

- In August 2009, Heat I and UM entered into a second amendment ("Amendment 2") to License Agreement UMSS-114A to extend the foregoing payment due dates for all past due license fees and patent costs.

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

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

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

- On December 7, 2020, the Company entered into separate amendments to its existingthree license agreements with the University of Miami to extend to December 31, 2025, the date by which the University of Miami may terminate the license agreements if by such date the Company will not have introduced a licensed product into the commercial marketplace in one of the three major markets (European Union, Japan and the United States) or will not have made best efforts to achieve the same. The three license agreements so amended are: (i) License Agreement (UMSS-114 (previously UM 97-14)) between the University of Miami and Heat Biologics, Inc. effective July 11, 2008, (ii) License Agreement (D-107) between the University of Miami and Heat I, Inc. effective February 18, 2011, and (iii) License Agreement (UMSS-114A) between the University of Miami and Heat I, Inc. effective February 18, 2011.

- *University of Miami - Pelican*

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

License 0331, 0539:

- Pelican is obligated to make milestone payments as follows: $150,000 due upon submission and approval of an IND and the completion of a Phase 1 clinical trial and $250,000 due upon the earlier of May 2024 or approval of an NDA. The Company has the right to terminate this Agreement without obligation for future unpaid milestones.

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

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

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

License I176:

- On December 12, 2010, Pelican entered into another license agreement ("I176") with UM for one component of complimentary technology to the July 11, 2008 agreement. Pelican agreed to pay UM a license fee of $50,000 and a reimbursement of $15,797 for past patent fees. Pelican also agreed to make a minimum royalty payment of $10,000 during 2012 through 2014 and then $20,000 every year thereafter. Pelican is obligated to make milestone payments as follows: $150,000 due upon submission and approval of an IND and the completion of a Phase 1 clinical trial and $500,000 due upon the earlier of May 2024 or approval of an NDA. The Company has the right to terminate this Agreement without obligation for future unpaid milestones.

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

- On December 7, 2020, the Company entered into a separate amendment to License Agreement (UMI-176) between the University of Miami and Heat Biologics, Inc. effective December 12, 2010, to extend to December 31, 2025, the date by which the University of Miami may terminate the license agreements if by such date the Company will not have introduced a licensed product into the commercial marketplace in one of the three major markets (European Union, Japan and the United States) or will not have made best efforts to achieve the same.

- *Other License Agreements*

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

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

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

a low likelihood of success for any technology at such stage, there can be no assurance that any products will be developed by Shattuck or that the Company will derive any revenue from Shattuck.

- On December 31, 2020, Zolovax, Inc. ("Zolovax"), a wholly-owned subsidiary of Heat Biologics, Inc. entered into an Exclusive License Agreement with the University of Miami for the license and development of a portfolio of patents leveraging its UMIP-510 platform to target the COVID-19 virus and other infectious diseases. The License Agreement grants Zolovax exclusive, worldwide rights to research, develop, make, use or sell Licensed Products (as defined in the License Agreement) based upon patent-related rights. The term of the license is the later of the length of the last to expire patent or fifteen (15) years from the date of the first sale of a Licensed Product unless terminated earlier. As consideration for the rights granted in the License Agreement, Zolovax paid an upfront fee of $2,500, is obligated to pay certain annual payments and to pay royalties equal to a percentage (in the low-to-mid single digits) of net sales of Licensed Products. These royalty rates are subject to reduction if additional license rights from third parties are required to commercialize the Licensed Products.

Future minimum royalty payments by the Company for licenses as of December 31, 2021 are as follows (in thousands):

Year ended December 31,	
2022	$ 34,000
2023	74,000
2024	775,000
2025	25,000
2026	50,000
Total	$ 958,000

10. Grant Revenue

In June 2016, Pelican entered into a cancer research grant contract or Grant Contract with CPRIT, under which CPRIT awarded a grant not to exceed $15.2 million for use in developing cancer treatments by targeting a novel T-cell costimulatory receptor (namely, DR3/TNFRSF25). The Grant Contract initially covered a period from June 1, 2016 through November 30, 2019, as amended, was extended to May 30, 2022. The first tranche of funding of $1.8 million was received in May 2017, a second tranche of funding of $6.5 million was received in October 2017, and a third tranche of funding of $5.4 million was received in December 2019. The remaining $1.5 million will be awarded on a reimbursement basis after we have fulfilled every requirement of the grant and the grant has been approved to be finalized.

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

Through December 31, 2021, $13.7 million of grant funding received to date has been recognized as revenue. As of December 31, 2021, we had a grant receivable balance of $1.3 million for CPRIT proceeds not yet received but for which the costs had been incurred or the conditions of the award had been met. At the conclusion of the grant the Company will be subject to an audit by CPRIT before the final grant payment can be approved and distributed. The Company believes this will not be finalized until 2023.

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

11. Stockholders' Equity

Authorized Capital

Heat has authorized 10,000,000 shares of Preferred Stock (par value $0.0001) as of December 31, 2021 and 2020. As of December 31, 2021 and 2020, there were no outstanding shares of Preferred Stock.

Heat had 250,000,000 shares of common stock (par value $0.0002) authorized as of December 31, 2021 and 2020. On March 20, 2020, an amendment to the Company's third amended and restated certificate of incorporation to increase the authorized shares of common stock to 250,000,000 was filed. On December 10, 2020, Heat announced a reverse stock split of its shares of common stock at a ratio of 1-for-7. The reverse stock split took effect as of 12:01 a.m. ET on December 11, 2020, to trade on a post-split basis at the market open on December 11, 2020. During the Company's annual shareholder meeting held February 27, 2020, 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 7 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 159.8 million shares to approximately 22.8 million at the time of the split. As of December 31, 2021, and 2020, 25,649,824 and 22,832,428 common stock shares were issued and outstanding.

Underwritten Registered Offering

On January 21, 2020, the Company closed on a public offering consisting of 2,857,142 shares of common stock together with Warrants to purchase 1,428,571 shares of common stock. The gross proceeds to the Company from this offering were approximately $7,000,000, before deducting underwriting discounts, commissions, and other offering expenses of approximately $550,000.

The Company has accounted for the warrants as liabilities and recorded them at fair value in our consolidated balance sheets (see Note 2).

At-The-Market-Offering

From January 1, 2021 to December 31, 2021 the Company sold approximately 2,106,027 shares of common stock under the Common Stock Sales Agreement, and the Amended and Restated Common Stock Sales Agreement, at an average price of approximately $ 12.18 per share, raising aggregate net proceeds of approximately $25.6 million, after deducting an aggregate commission up to 3%.

From January 1, 2020 to December 31, 2020 the Company sold approximately 13,175,677 shares of common stock under the Common Stock Sales Agreement, and the Amended and Restated Common Stock Sales Agreement, at an average price of approximately $ 8.69 per share, raising aggregate net proceeds of approximately $114.4 million, after deducting an aggregate commission up to 3%.

Common Stock Warrants

In connection with the November 26, 2018 public offering, the Company issued 657,142 common stock warrants each of which are exercisable for one share of common stock. The common stock warrants have an exercise price of $11.55 per share and expire five years from the issuance date. The warrants have been accounted for as equity instruments.

In connection with the May 7, 2018 public offering, the Company issued 1,357,142 pre-funded warrants and 1,026,785 common stock warrants each of which are exercisable for one share of common stock. The pre-funded warrants had an exercise price of $0.07 per share and as of December 31, 2019 all pre-funded warrants have been exercised. The common stock warrants have an exercise price of $11.09 per share and expire five years from the issuance date. The warrants have been accounted for as equity instruments.

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

In January 2021, the Company issued 31,000 common stock warrants each of which are exercisable for one share of common stock. The common stock warrants have an exercise price of $5.78 per share and expire two years from the issuance date. The warrants have been accounted for as equity instruments.

During the year ended December 31, 2021, no common stock warrants have been exercised or exchanged and 42,556 common stock warrants expired. During the year ended December 31, 2020, 1,959,735 common stock warrants have been exercised and exchanged and no common stock warrants expired.

The Company has a total of 747,383 warrants outstanding at a weighted average exercise price of $11.06 to purchase its common stock as of December 31, 2021. These warrants are summarized as follows:

Issuance Date	Number of Shares	Exercise Price	Expiration Date
5/7/2018	403,025	$ 11.09	5/8/2023
11/26/2018	313,358	$ 11.55	11/26/2023
1/28/2021	31,000	$ 5.78	1/28/2023

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

	Common Stock Warrants
Outstanding, December 31, 2019	1,290,103
Issued	1,428,571
Exercised	(1,489,497)
Exchanged	(470,238)
Outstanding, December 31, 2020	758,939
Issued	31,000
Expired	(42,556)
Outstanding, December 31, 2021	747,383

Equity Compensation Plans

2009 Stock Incentive Plan

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

The Company amended the 2009 Stock Option Plan and all related addendum agreements in April 2011. This second amendment increased the number of shares available for issuance from 21,739 to 65,217. The Company amended the 2009 Plan to increase the number of shares available for issuance to 86,957. The 2009 Plan expired in September 2019, however all options outstanding at the time of expiration remained outstanding and exercisable by their term. As of December 31, 2021 and 2020, there were 2,622 and 6,378 stock options outstanding under the 2009 Plan, respectively.

2014 Stock Incentive Plan

In June 2014, the stockholders approved the Heat Biologics, Inc. 2014 Stock Option Plan (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 to300,000 awards in total. As of December 31, 2021 and 2020, there were 21,368 and 30,354 stock options outstanding under the 2014 Plan, respectively.

2017 Stock Incentive Plan

In June 2017, the stockholders approved the Heat Biologics, Inc. 2017 Stock Incentive Plan (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, 2021 and 2020 there were 38,227 and 42,932 stock options outstanding under the 2017 Plan, respectively.

2018 Stock Incentive Plan

In October 2018, the stockholders approved the Heat Biologics, Inc. 2018 Stock Incentive Plan (the "2018 Plan"), under which the Company is authorized to grant 571,428 awards in the form of both incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock-based awards with terms established by the Compensation Committee of the Board of Directors which has been appointed by the Board of Directors to administer the 2018 Plan. At our 2019 Annual Meeting of Stockholders, the stockholders approved an amendment to the 2018 Plan to increase the number of shares by 571,428. As of December 31, 2021 and 2020 there were 2,847,755 and 1,400,475 stock options outstanding under the 2018 plan, respectively.

There are 358,897 stock options remaining available for grant under the 2009 Plan, 2014 Plan, 2017 Plan and 2018 Plan (collectively, the "Plans"). The following table summarizes the components of the Company's stock-based compensation included in net loss:

	For the years ended December 31,	
	2021	2020
Employee stock options	$ 1,136,843	$ 4,966,596
Non-employee stock options	1,294,279	158,963
Employee stock awards	2,903,463	1,072,506
Non-employee stock awards	834,396	179,792
	$ 6,168,981	$ 6,377,857

Accounting for Stock-Based Compensation:

Stock Compensation Expense - For the years ended December 31, 2021, and 2020, we recorded $6,168,981, and $6,377,857 of stock-based compensation expense, respectively. No compensation expense of employees with stock awards was capitalized during the years ended December 31, 2021 and 2020.

Stock Options - Under the Plans, we have issued stock options. A stock option granted gives the holder the right, but not the obligation to purchase a certain number of shares at a predetermined price for a specific period of time. We typically issue options that vest over four years in equal installments beginning on the first anniversary of the date of grant. Under the terms of the Plans, the contractual life of the option grants may not exceed ten years. During the years ended December 31, 2021, and 2020, we issued options that expire ten years from the date of grant.

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

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

The following weighted-average assumptions were used for option grants during the years ended December 31, 2021 and 2020:

- ***Volatility*** – The Company used an average historical stock price volatility of its own data plus an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms.

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

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

- ***Dividend yield*** – The expected dividend yield was considered to be0% in the option pricing formula since the Company had not paid any dividends and had no plan to do so in the future.

- ***Forfeitures*** – The Company's policy is to account for forfeitures as they occur.

The following table summarizes assumptions used in our calculations of fair value for the years ended December 31, 2021 and 2020:

	2021	2020
Dividend yield	— %	— %
Expected volatility	99.34-104.61 %	83.13-101.68 %
Risk-free interest rate	0.36-1.36 %	0.26-1.69 %
Expected lives (years)	5.0-6.1 years	5.4-6.3 years

Stock Option Activity - The weighted-average grant date fair value of options granted during the years ended December 31, 2021 and 2020, as determined under the Black-Scholes valuation model, was $3.67 and $5.92, respectively.

The following table summarizes stock option activity for the years ended December 31, 2021 and 2020:

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Stock options outstanding at December 31, 2019	437,603	$ 17.90	$ 44,196	
Granted	1,167,749	7.90		
Exercised	(7,140)	3.99	9,813	
Cancelled and expired	(118,073)	5.80		
Stock options outstanding at December 31, 2020	1,480,139	$ 11.05	$ 9,213	
Granted	1,674,153	4.65		
Exercised	(70,967)	6.53	—	
Expired	(49,532)	14.26		
Forfeited	(79,478)	5.55		
Stock options outstanding at December 31, 2021	2,954,315	$ 7.62	$ 100,419	9.02 Years
Stock options exercisable at December 31, 2021	1,161,021	$ 12.12	$ 37,130	8.22 Years

Unrecognized compensation expense related to unvested stock options was $5.9 million as of December 31, 2021, which is expected to be recognized over a weighted-average period of 1.57 years and will be adjusted for forfeitures as they occur.

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

Restricted Stock Activity - The following table summarizes the restricted stock activity during the years ended December 31, 2021 and 2020:

	Shares	Weighted Average Fair Value
Restricted stock at December 31, 2019	179,505	$ 5.99
Granted	339,999	3.22
Vested	(275,115)	4.27
Cancelled	(4,461)	7.42
Restricted stock at December 31, 2020	239,928	$ 4.02
Granted	678,490	5.09
Vested	(548,248)	4.88
Restricted stock at December 31, 2021	370,170	$ 4.71

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

The following table summarizes the RSU activity during the years ended December 31, 2021 and 2020:

	Shares	Weighted Average Fair Value
RSUs at December 31, 2019	4,291	$ 30.29
Vested	(2,342)	33.15
Cancelled	(49)	36.57
RSUs at December 31, 2020	1,900	$ 26.60
Vested	(1,900)	26.60
Cancelled	—	—
RSUs at December 31, 2021	—	$ —

12. Income Tax

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statements carrying amounts of assets and liabilities and their respective tax bases, operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which

those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In accordance with FASB ASC 740, Accounting for Income Taxes, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2021 and 2020, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying consolidated statements of operations. As of December 31, 2021 and 2020, the Company had no such accruals.

The components of income tax expense (benefit) are as follows:

	2021	2020
Current Expense:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	—	—
Deferred Expense:		
Federal	$ (145,974)	$ —
State	—	—
Foreign	—	—
Total	$ (145,974)	$ —

The differences between the company's income tax expense and the expense computed at the21% United States statutory income tax rate were as follows:

	2021	2020
Federal income tax expense at statutory rate:	$ (7,465,000)	$ (5,540,000)
Increase (reduction) in income tax resulting from:		
State Income Taxes	556,000	833,000
Foreign Rate Differential	(16,000)	5,000
Nondeductible Expenses	1,000	210,000
Research & Development Credit	(836,000)	(682,000)
Stock Based Compensation	164,000	113,000
Excess Executive Compensation	259,000	248,000
Payout of Contingent Consideration	—	421,000
Goodwill Impairment	305,000	—
Reserve for Loss Carryforwards Limited by Sec. 382	8,000	15,270,000
Other	(32,974)	(41,000)
Increase in Valuation Allowance	6,911,000	(10,837,000)
	$ (145,974)	$ —

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

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, 2021 and December 31, 2020:

	2021	2020
Deferred tax assets:		
Net Operating Losses	$ 17,830,889	$ 13,012,193
R&D Credits	2,538,168	1,528,044
Stock Compensation	2,344,902	1,931,784
Contingent Consideration	767,763	668,994
Deferred Revenue	8,039	—
Unrealized Gains/Losses	210,300	—
Deferred tax assets	23,700,061	17,141,015
Deferred tax liabilities:		
Intangible Assets	(803,937)	(1,347,399)
Property, plant and equipment, primarily due to differences in depreciation	(83,122)	(69,882)
Lease Liability	(78,035)	(99,761)
Other Accrued Expenses	(83,931)	(29,781)
Deferred tax liabilities	(1,049,025)	(1,546,823)
Valuation allowance	(22,866,973)	(15,956,103)
Net deferred tax (liabilities)	$ (215,937)	$ (361,911)

At December 31, 2021 and December 31, 2020, 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 company completed a 382 analysis to determine any limitations on the annual usage of their NOL carryforwards (discussed in further detail below). As a result of this reserve analysis, the valuation allowance was decreased from $32,484,566 to $15,956,103 at December 31, 2020. The allowance increased to $22,866,973 at December 31, 2021. Net Operating Losses created in years beginning after 2017 now only offset 80% of Taxable Income but no longer have a 20 year expiration. As such, NOL's created after 2017 can be used to offset indefinite lived liabilities up to 80%.

At December 31, 2021, the Company has federal net operating loss carryforwards of approximately $145,217,000, including $3,027,284 acquired from Pelican Therapeutics. However, due to Section 382 limitations (discussed in further detail below), only $84,582,770 of the NOLs are available to offset future taxable income. The federal net operating loss carryforwards begin to expire in 2029. The Company has various state net operating loss carryforwards totaling approximately $126,400,000 including $2,464,819 from Pelican Therapeutics. However, due to Section 382 limitations (discussed in further detail below), only approximately $60,188,000 of the NOLs are available to offset future state taxable income. State net operating losses begin to expire in 2024. On November 15, 2021, the North Carolina General Assembly passed Senate Bill 105 eliminating the current 2.5% corporate income tax by phased lowering of the rate from 2025 – 2030. An additional reserve has been set up for North Carolina NOLs that are not expected to be used by 2030. The Company has various foreign net operating loss carryforwards of approximately $139,196. The foreign net operating loss carryforwards are carried forward indefinitely. Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by U.S. federal, state, and foreign income tax authorities.

In accordance with FASB ASC 740, Accounting for Income Taxes, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2021 and 2020, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of income. As of December 31, 2021 and 2020, the Company had no such accruals

The Company files income tax returns in the United States, various state and foreign jurisdictions. The Company is subject to examination by taxing authorities for the tax years ended December 31, 2009 through 2020.

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 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.

During the course of preparing the Company's consolidated financial statements as of and for the year ended December 31, 2021, the Company completed an assessment of the available NOL and tax credit carryforwards under Sections 382 and 383, respectively, of the Code. The Company determined that it underwent multiple ownership changes throughout its history as defined under Section 382, including most recently in 2020. As a result of the identified ownership changes, the portion of NOL and tax credit carryforwards attributable to the pre-ownership change periods are subject to a substantial annual limitation under Sections 382 and 383 of the Code. The Company has adjusted its previously reported NOL and tax credit carryforwards to address the impact of the 382 ownership changes. This resulted in a reduction of available federal and state NOLs of $58.2 million and $64.1 million, respectively. The write down of the NOLs reduced the net operating losses line as of December 31, 2020 within gross deferred tax assets as previously disclosed by $13.5 million, with a corresponding decrease in the valuation allowance. The Company also reduced its tax credit carryforwards as of December 31, 2020 within gross deferred tax assets by $3 million with a corresponding decrease in the valuation allowance.

Since the limitation affected the prior period, the Company has determined that itsDecember 31, 2020tax footnote presentation overstated the gross deferred tax asset and corresponding valuation allowance by $16.5 million. However, there wasnonet impact to the net deferred tax asset and tax expense as the decrease in the net operating loss and tax credit carryforwards was offset completely by a corresponding adjustment to the Company's overall valuation allowance. For comparative purposes, the Company's prior year tax footnote has been revised to reflect the adjustment to the net operating losses, tax credits and valuation allowance. The revision had no effect on the previously reported balance sheets, statements of operations and comprehensive loss, cash flows and stockholders' equity.

13. Leases

The Company accounts for its leases under ASC 842. The Company has determined that its leases for office and laboratory space without optional terms or variable components, are operating leases.

The Company conducts its operations from leased facilities in Morrisville, North Carolina, San Antonio, Texas and New Brunswick, New Jersey, the leases for which will expire in 2027, 2023 and 2022. The leases are for general office space and lab space and require the Company to pay property taxes, insurance, common area expenses and maintenance costs.

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

In June 2021, the Company entered into a lease agreement with Durham KTP Tech 7, LLC, to lease a 15,996 square foot facility in Morrisville, North Carolina to expand its research and development activities. The lease has a term of eight years following the commencement date and provides the Company the option to extend the lease term for one five year term. It is subject to fixed rate escalation increases and also provides up to $2.4 million for tenant improvements. As the lease commencement date under ASC 842 had not occurred as of December 31, 2021, the Company has not recorded an operating lease ROU asset or lease liability for this lease in the accompanying consolidated balance sheets. The initial estimate of the minimum amount of undiscounted lease payments due under this lease is $4.66 million. Further, the tabular disclosure of minimum lease payments below does not include payments due under this lease.

In October 2021, Scorpion entered into a lease agreement with Merchants Ice II, LLC, to lease a 20,144 square foot facility in San Antonio, TX for general office, laboratory, research, analytical, and/or biomanufacturing purposes. Merchants Ice II, LLC is a nonprofit entity investing in the building with the intention to encourage development of emerging technologies. As a result, investments made to the building could generate tax incentives under the New Market Tax Credit ("NMTC") program. Scorpion agreed that all investments and expenditures qualifying under the NMTC (i.e., certain equipment and building improvements) would be purchased by the Merchants Ice II, LLC to generate the largest possible tax incentive and Scorpion would reimburse Merchant Ice, LLC for these payments. To date, Scorpion has reimbursed Merchant Ice, LLC $12.2 million which is shown in "Other assets" on the consolidated balance sheets. Upon lease commencement, these assets will be classified as a right-of-use asset. The lease has a term of fifteen years following the commencement date and provides Scorpion the option to extend the lease term for one fifteen-year term, and one subsequent ten year term upon expiration of the first extended term. It is subject to fixed rate escalation increases and also provides up to $2.4 million for tenant improvements. As the lease had not commenced as of December 31, 2021, Scorpion has not recorded a right-of-use asset or lease liability for this lease in the accompanying consolidated balance sheets. The initial estimate of the minimum amount of undiscounted lease payments due under this lease is $11.1 million.

Total cash paid for operating leases during the year ended December 31, 2021 and 2020 was $0.4 million and $0.3 million and is included within cash flows from operating activities within the consolidated statement of cash flows.

The Company leases furniture and specialized lab equipment under finance leases. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset. The effective interest rate was 5.52% and 6.17% for the years ended December 31, 2021 and 2020.

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

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020
Operating lease cost	$ 474,135	$ 435,024
Finance lease cost		
Amortization of lease assets	185,171	114,201
Interest on lease liabilities	21,970	17,972
Total finance lease cost	$ 207,141	$ 132,173

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

The weighted average remaining lease term and incremental borrowing rate as of December 31, 2021 and 2020 were as follows:

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020
Weighted average remaining lease term		
Operating leases	5.0 years	5.9 years
Finance leases	2.0 years	2.0 years
Weighted average discount rate		
Operating leases	6.32 %	6.49 %
Finance leases	5.30 %	6.17 %

Maturities of operating and finance lease liabilities as of December 31, 2021 were as follows:

	Operating Leases	Finance Leases	Total
2022	$ 426,539	281,042	707,581
2023	292,921	135,632	428,553
2024	231,503	131,256	362,759
2025	238,452	-	238,452
2026	245,607	-	245,607
2027	209,214	-	209,214
Thereafter	-	-	-
Total minimum lease payments	1,644,236	547,930	2,192,166
Less: imputed interest	(233,037)	(31,927)	(264,964)
Present value of lease liabilities	$ 1,411,199	$ 516,003	$ 1,927,202

Maturities of operating and finance lease liabilities as of December 31, 2020 were as follows:

	Operating Leases	Finance Leases	Total
2021	$ 369,995	$ 120,684	$ 490,679
2022	360,839	155,694	516,533
2023	244,973	10,284	255,257
2024	231,503	-	231,503
2025	238,452	-	238,452
Thereafter	454,820	-	454,820
Total minimum lease payments	1,900,582	286,662	2,187,244
Less: imputed interest	(320,193)	(18,295)	(338,488)
Present value of lease liabilities	$ 1,580,389	$ 268,367	$ 1,848,756

14. Related Party Transactions

The Company compensates its board members. Board members received cash compensation between approximately $61,500 and $315,000, for services rendered during 2021 and 2020. Board members also received equity compensation.

See Note 4 about future milestone payments that may be paid to Participating Pelican Shareholders.

15. 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.

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

Common equivalent shares consist of stock options, restricted stock units, and warrants that are computed using the treasury stock method.

For the years ended December 31, 2021 and 2020, all of the Company's common stock options, unvested restricted stock units and warrants are anti-dilutive and therefore have been excluded from the diluted net loss per common share calculation.

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

	For the Year Ended December 31,	
	2021	2020
Net loss	$ (35,400,807)	$ (26,381,389)
Net loss - Non-controlling interest	(329,339)	(331,652)
Net loss attributable to Heat Biologics, Inc.	$ (35,071,468)	$ (26,049,737)
Weighted-average common shares outstanding, basic and diluted	24,913,942	15,982,568
Net loss per share, basic and diluted	$ (1.41)	$ (1.63)

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

	2021	2020
Outstanding stock options	2,954,315	1,480,139
Restricted stock subject to forfeiture and restricted stock units	370,170	241,828
Outstanding common stock warrants	747,383	758,939

16. Subsequent Events

Management has evaluated all subsequent events through the date the consolidated financial statements were issued.

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

As of December 31, 2020, Heat Biologics, Inc. (the "Company," "we," "us," and "our") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which is our common stock, par value $0.0002 per share (the "common stock").

General

The following is a description of the material terms of our common stock. This is a summary only and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Third Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), and our Amended and Restated Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, of which this Exhibit is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law, for additional information.

Description of Common Stock

Authorized Shares of Common Stock. We currently have authorized 250,000,000 shares of common stock.

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

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

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

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

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

Stockholder Rights Plan

On March 11, 2018, our board of directors declared a dividend of one Right for each outstanding share of our common stock, which was amended by Amendment No. 1 thereto dated March 8, 2019, Amendment No. 2 thereto dated March 10, 2020, Amendment No. 3 thereto dated March 8, 2021 to, among other things, extend the expiration date of the stockholder's rights plan to March 11, 2022 and Amendment No. 4 thereto to extend the expiration date of the stockholder's rights plan to March 11, 2023. The dividend was initially paid on March 23, 2018 (the "Record Date") to the stockholders of record at the close of business on that date. Each Right initially entitles the registered holder to purchase from us one share of common stock at a price set forth therein (the "Purchase Price"), subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement, dated as of March 11, 2018, as amended by Amendment No. 1 thereto dated March 8, 2019, Amendment No. 2 thereto dated March 10, 2020, Amendment No. 3 thereto dated March 8, 2021 and Amendment No. 4 dated March 11, 2022, as the same may be

further amended from time to time (the "Rights Agreement"), between the Company and Continental Stock Transfer & Trust Company, as Rights Agent (the "Rights Agent").

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

The Rights Agreement provides that, until the Distribution Date (or earlier expiration of the Rights), the Rights will be transferred with and only with the common stock. Until the Distribution Date (or earlier expiration of the Rights), new common stock certificates issued after the Record Date upon transfer or new issuances of common stock will contain a notation incorporating the Rights Agreement by reference. Until the Distribution Date (or earlier expiration of the Rights), the surrender for transfer of any certificates for shares of common stock (or book entry shares of common stock) outstanding as of the Record Date, even without such notation or a copy of the Summary of Rights, will also constitute the transfer of the Rights associated with the shares of common stock represented thereby. As soon as practicable following the Distribution Date, separate certificates evidencing the Rights ("Right Certificates") will be mailed to holders of record of the common stock as of the close of business on the Distribution Date and such separate Right Certificates alone will evidence the Rights. The Rights are not exercisable until the Distribution Date. The Rights will expire at the close of business on March 11, 2023, unless the Rights are earlier redeemed or exchanged by the Company as described below.

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

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

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

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

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

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

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

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

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

Potential Anti-Takeover Effects

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

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

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

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

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

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

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

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

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

Delaware Takeover Statute

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

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

Listing of Common Stock on the Nasdaq Capital Market

Our common stock is currently listed on the NYSE American LLC under the trading symbol “HTBX.”

Transfer Agent

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

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS EXHIBIT MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

LICENSE AGREEMENT

This License Agreement (the "Agreement") is entered into and made effective the 11th day of July, 2008 (the "Effective Date") between UNIVERSITY OF MIAMI and its School of Medicine, whose principal place of business is at 1600 N.W. 10th Avenue, Miami, Florida 33136 (hereinafter referred to as "LICENSOR") and HEAT BIOLOGICS II, INC., a Delaware corporation, whose principal place of business is at Atlantic Center, 119 Washington Avenue, Suite 401, Miami Beach, FL 33139 (hereinafter referred to as "LICENSEE").

WITNESSETH

WHEREAS, LICENSOR is the sole owner of the technology and product identified as the Podack Antibody Technology (UM03-31, UM05-39);

WHEREAS. LICENSOR is the sole owner of the patent rights relating to the Podack Antibody Technology (UM03-31, UM05-39);

WHEREAS LICENSOR wishes to exclusively license to LICENSEE the Podack Antibody Technology (UM03-31, UM05-39) and patent rights related thereto; and

WHEREAS, LICENSEE desires to acquire an exclusive license from LICENSOR to the Podack Antibody Technology (UM03-31, UM05-39) and patent rights related thereto for the purpose or commercially marketing the Podack Antibody Technology (UM03-31, UM05-39).

NOW THEREFORE, for these and other valuable considerations. the receipt of which is hereby acknowledged, the parties agree as follows:

1. DEFINITIONS:

1.1 "Affiliate" shall mean any corporation or other business entity controlled by, controlling or under common control with LICENSEE. For this purpose, "control" shall mean direct or indirect beneficial ownership of at least a fifty percent (50%) of the voting stock of, or at least a fifty percent (50%) interest in the income of such corporation or other business entity, or such other relationship as in fact, constitutes actual control.

1.2 "Sublicensee" as used in this Agreement shall mean any third party to whom LICENSEE has granted a license to make, have made, use and/or sell the Product under the Patent Rights, provided said third party has agreed in writing with LICENSEE to accept the conditions and restrictions agreed to by LICENSEE in this Agreement.

1.3 "Patent Rights" shall mean the following United States Patent applications: U.S. patent application serial number 10/923,373 entitled 'COMPOSITIONS AND METHODS FOR TREATING INFLAMMATORY LUNG DISEASE" and filed on August 24, 2004; US Provisional Patent Applications series lumbers 60/496,555 and 60/496,625 both filed on August 20, 2003; US Patent Application serial number 11/512,412 entitled "IMMUNOMODULATING TUMOR NECROSIS FACTOR FOR RECEPTOR 25 (TNFR25) AGONISTS, ANTAGONISTS AND IMMUNOTOXINS" and filed on August 30, 2006; US Provisions Patent Application serial number 60/712,084 filed on August 30, 2005; all United States Patents and foreign patents and patent applications claiming the priority dates of these U.S. applications; all divisionals, continuations of the foregoing; and those claims in the continuations-in-part of the numbers 10/923,373; 60/496,555; 60/496,625; 11/512,412; or 60/712,084 to meet the requirements of 35 U.S.C. 112 1; and any re-examinations or reissues of the foregoing

1.4 "Licensed Product" shall mean any product or part thereof which:

(a) is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights;

(b) is manufactured by using a process which is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights; or

(c) incorporates or comprises the Licensed Materials.

1.5 "Licensed Process" shall mean any process practiced in a country in which said process is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or pending claim contained in the Patent Rights.

1.6 "Net Sales" shall mean the sum of all amounts invoiced on account of sale or use of Licensed Products and Licensed Processes by LICENSEE and its

Affiliates or any Sublicensees to non-affiliated third party purchasers or users of Licensed Products or Licensed Processes, less (a) discounts to purchasers in amounts customary in the trade, (b) amounts for transportation or shipping charges to purchasers, (c) credits for returns, allowances or trades, and (d) taxes and duties levied on the sale or use of Licensed Products, whether absorbed by Licensee or paid by the purchaser.

1.7 "Territory" shall mean worldwide.

1.8 "Field of Use" shall mean all human healthcare and research applications.

1.9 "Licensed Materials" shall mean LICENSOR's biological materials in the possession of Dr. Eckhard Podack's laboratory at the Effective Date that are covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights.

1.10 "LICENSEE Materials" shall mean any biological materials (e.g., humanized monoclonal antibodies) that LICENSEE makes or has made using Licensed Materials or sequence information from any polynucleotides or polypeptides contained in the Licensed Materials.

2. GRANT:

2.1 LICENSOR hereby grants to LICENSEE an exclusive license, subject to any rights of the U.S. government specified in section 4 below, in the Territory for the Field of Use, with the right to sublicense, under the Patent Rights, to make, have made for its own use and sale, use and sell Licensed Products and Licensed Processes.

2.2 LICENSOR also hereby grants to LICENSEE an exclusive license to make, use, and/or sell the Licensed Materials in the Territory for the Field of Use. At LICENSEE's request, LICENSOR shall provide LICENSEE with a reasonable amount of Licensed Materials so that LICENSEE may reproduce such Licensed Materials for the purpose of making, selling, or using Licensed Products or Licensed Processes.

2.3 LICENSOR reserves to itself the non-transferable right to make and use Licensed Materials, Licensed Products and/or Licensed Processes solely for its internal, non-commercial: scientific research, not-for-profit clinical research, and educational purposes. Except to the extent required by law, LICENSOR shall not transfer

the Licensed Materials for the purpose of making the Licensed Materials to any third party without first obtaining, in a Material Transfer Agreement, the written agreement of that third party to not use or further distribute such materials for commercial purposes. LICENSOR shall notify LICENSEE in writing of any third party request for such materials and provide LICENSEE at least ten (10) days to object to such request on the basis that such transfer would interfere with the objectives of this Agreement.

2.4 LICENSEE hereby grants to LICENSOR the non-transferable right to make and use LICENSEE Materials solely for its internal, non-commercial scientific research, not-for-profit clinical research, and educational purposes. At LICENSOR's request, LICENSEE shall provide LICENSOR with a reasonable amount of LICENSEE Materials solely for the aforesaid purpose. Without the express written consent of LICENSEE, LICENSOR shall not transfer to a third party any LICENSEE Materials or derivatives thereof or any non-public sequence information from any polynucleotides or polypeptides contained in the foregoing.

3. TERM:

The license granted by this Agreement shall be exclusive in the licensed Field of Use for a term commencing as of the Effective Date of this Agreement and continue until the expiration, on a country by country basis, of all of the Patent Rights.

4. **UNITED STATES LAWS:**

4.1 Licensee understands that the Licensed Subject Matter may have been developed under a funding agreement with the Government of the United States of America and, if so, that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to the Government's rights under any agreement and any applicable law or regulation. If there is a conflict between an agreement, applicable law or regulation and this Agreement, the terms of the Government agreement, applicable law or regulation shall prevail.

Specifically, This Agreement is subject to all of the terms and conditions of Title 35 United States Code sections 200 through 204, including an obligation that Licensed Product(s) sold or produced in the United States be

"manufactured substantially in the United States," and LICENSEE agrees to take all reasonable action necessary on its part as licensee to enable LICENSOR to satisfy its obligation thereunder, relating to Invention(s).

4.2 It is understood that LICENSOR is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the Export Administration Act of 1979), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by LICENSEE that LICENSEE shall not export data or commodities to certain foreign countries without prior approval of such agency. LICENSOR neither represents that a license shall not be required nor that, if required, it shall be issued.

5. PATENT PROTECTION AND INFRINGEMENT:

5.1 LICENSOR, during the term of this Agreement, is responsible for the filing and the prosecution of all patents and applications where LICENSEE shall reimburse LICENSOR for all payments within thirty (30) days of invoice. LICENSOR shall keep LICENSEE fully apprised on the status of all Patent Rights and shall provide LICENSEE the opportunity to make comments and suggestions on all decisions relating to the prosecution of the Patent Rights (e.g., office actions). LICENSOR shall in good faith consider incorporating such comments and suggestions unless such incorporation would be contrary to the purposes of this Agreement.

5.2 LICENSEE shall promptly notify LICENSOR in writing of any claim of Patent Rights infringement which may be asserted against LICENSEE or LICENSOR, its Affiliates and any sublicensees because of the manufacture, use, promotion and sale of Products.

5.3 LICENSEE shall pay to LICENSOR a license issue fee in the amount of [*****] and past patent fees in an amount of [*****] within one (1) year of the Effective Date, which sum, among other things, shall be considered full consideration for the preparation, filing, prosecution.

5.4 LICENSEE will defend, indemnify and hold harmless LICENSOR, its trustees, officers, directors, employees and its Affiliates against any and all judgments and damages arising from any and all third party claims of Patent Rights infringement which may be asserted against LICENSOR, and Affiliates because of the manufacture, use, promotion and sale of Licensed Products. LICENSEE will bear all costs and expenses incurred in connection with the defense of any such claims or as a result of any settlement made or judgment rendered on the basis of such claims. LICENSOR shall have no further liability to LICENSEE for any loss or damages LICENSEE may incur as a result of the invalidity of LICENSOR'S Patent Rights. LICENSOR will have the right, but not the obligation to retain counsel at its expense in connection with any such claim. LICENSOR at its option, shall have the right, within thirty days after commencement of such action, to intervene and take over the sole defense of the action at its own expense.

5.5 Upon learning of any infringement of Patent Rights by third parties in any country, LICENSEE and LICENSOR will promptly inform each other, as the case may be, in writing of that fact and will supply the other with any available evidence pertaining to the infringement. LICENSEE at its own expense, shall have the option to take whatever steps are necessary to stop the infringement at its expense and recover damages therefore. If requested by LICENSEE, LICENSOR will join in any legal actions enforcing or defending the Patent Rights against third parties deemed necessary or advisable by LICENSEE to prevent or seek damages, or both, from the infringement of the Patent Rights provided that LICENSEE funds all costs associated with such actions, using counsel mutually acceptable to LICENSEE and LICENSOR, and indemnifies and holds LICENSOR harmless with respect to any claims or damages made against or sustained by LICENSOR in connection with such involvement. In the event that LICENSOR and LICENSEE mutually bring suit, costs and expenses shall be borne by LICENSEE, and any recovery shall be shared by the parties as if such infringing sales were Net Sales. In any event, no settlement, consent, judgment or other voluntary final disposition of the suit may be entered into without the consent of LICENSOR, which shall not be unreasonably withheld. In the event LICENSEE does not take steps to stop the infringement, LICENSOR shall have the right to bring suit at its own expense. In such event, financial recoveries will be entirely retained by LICENSOR.

5.6 LICENSOR shall have no responsibility with respect to LICENSEE'S own trademarks and trade name, and LICENSEE in respect to the use thereof will defend, indemnify and hold harmless LICENSOR against any and all third party claims.

6. INDEMNIFICATION:

6.1 LICENSEE agrees to release, indemnify and hold harmless the LICENSOR, its trustees, officers, faculty, employees, Affiliates, agents and students against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including reasonable attorney's fees through the appellate levels) which may be brought against LICENSOR, its trustees, officers, faculty, employees, Affiliates, agents and/or students as a result of or arising out of any willful misconduct or negligent act or omission of LICENSEE, its agents, or employees, or arising out of use, production, manufacture, sale, lease, consumption or advertisement by LICENSEE or any third party, including any Sublicensee of any Licensed Product, Licensed Patent, Licensed Process, or Licensed Materials covered by this Agreement.

6.2 LICENSOR agrees to release and hold harmless the LICENSEE, its directors, officers, employees, Affiliates, Sublicensees, and agents against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including reasonable attorney's fees through the appellate levels) which may be brought against LICENSEE, its directors, officers, employees, Affiliates, Sublicensees, and/or agents as a result of or arising out of any willful misconduct, or negligent act or omission of LICENSOR; or, except where caused by LICENSEE's negligence or willful misconduct, arising out of use, sale, lease, consumption or advertisement by LICENSOR of any LICENSEE Materials covered by this Agreement.

6.3 This Agreement to reimburse and indemnify under the circumstances set forth above shall continue after the termination of this Agreement.

7. REPRESENTATIONS/WARRANTIES:

7.1 LICENSOR hereby represents and warrants to LICENSEE that LICENSOR owns the Patent Rights and Licensed Materials and has not assigned any

rights therein or given any license or other rights thereto to any party other than LICENSEE.

7.2 LICENSOR hereby represents and warrants that, although it has not conducted any investigation, it has no knowledge of any patents or patent applications, other than the Patents Rights, that contain a claim that would be infringed by the sale or use of a Licensed Product, Licensed Process, or Licensed Materials.

7.3 EXCEPT AS PROVIDED ABOVE, LICENSOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AND HEREBY DISCLAIMS ALL SUCH WARRANTIES, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE CONDITION OF ANY INVENTION(S) OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, LICENSED UNDER THIS AGREEMENT; OR THE MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE INVENTION OR PRODUCT; OR THAT THE USE OF THE LICENSED PRODUCT WILL NOT INFRINGE ANY PATENT, COPYRIGHTS, TRADEMARKS, OR OTHER RIGHTS. LICENSOR SHALL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY ANY LICENSEE OR ANY THIRD PARTIES RESULTING FROM THE USE, PRODUCTION, MANUFACTURE, SALE, LEASE, CONSUMPTION, OR ADVERTISEMENT OF THE PRODUCT.

7.4 The provisions of this Section shall continue beyond the termination of this Agreement.

8. ROYALTIES:

8.1 In consideration of the license herein granted, LICENSEE shall pay royalties to LICENSOR as follows:

(a) As specified in section 5.3, LICENSEE agrees to pay to LICENSOR a license issue fee of [*****] total, [*****] of the license issue fee shall be paid to LICENSOR within thirty (30) days of the Effective Date, and the remaining [*****] of the license issue fee shall be paid to LICENSOR within one (1) year of the Effective Date.

(b) LICENSEE agrees to pay LICENSOR minimum royalty payments, as follows:

Payment	Year
[$10,000]	2012
[$10,000]	2013
[$10,000]	2014
[$20,000]	2015 and every year thereafter on the same date, for the life of this Agreement.

The minimum royalty shall be paid for each year in which this Agreement is in effect. The minimum royalty payment shall be due on or before May 31 of the calendar year. Any minimum royalty paid in a calendar year will be credited against the earned royalties for that calendar year. It is understood that the minimum royalties will be applied to earned royalties on a calendar year basis, and that sales of Licensed Products and/or Licensed Processes requiring the payment of earned royalties made during a prior or subsequent calendar year shall have no effect on the annual minimum royalty due LICENSOR for other than the same calendar year in which the royalties were earned.

(c) LICENSEE agrees to pay to LICENSOR as earned royalties a royalty calculated as a percentage of LICENSEE's Net Sales of Licensed Products which, if not for this Agreement, would infringe the Patent Rights, in accordance with the terms and conditions of this Agreement. The royalty is deemed earned as of the earlier of the date the Licensed Product and/or Licensed Process is actually sold and paid for, the date an invoice is sent by LICENSEE, or the date a Licensed Product and/or Licensed Process is transferred to a

third party for any promotional reasons. The royalty shall remain fixed while this Agreement is in effect at a rate of [*****] of Net Sales.

(d) For a sublicense, LICENSEE shall pay to LICENSOR an amount equal to [*****] of what LICENSEE would have been required to pay to LICENSOR had LICENSEE sold the amount of Licensed Products sold by the Sublicensee. In addition, if LICENSEE receives any fees, minimum royalties, or other payments in consideration for any rights granted under a Sublicense, and such payments are not based directly upon the amount or value of Licensed Products or Licensed Processes sold by the Sublicensee nor represent payment of costs to LICENSEE for a development program which LICENSEE is obligated to perform under such sublicense, then LICENSEE shall pay LICENSOR [*****] of such payments.

(e) In addition to all other payments required under this Agreement, LICENSEE agrees to pay LICENSOR milestone payments, as follows:

Payment	Event
[$25,000]	Upon submission of an IND
[$25,000]	Upon approval of an IND
[$100,000]	Upon completion of a phase 1 clinical trial
[$500,000]	By the earlier of May 31, 2022 or the approval of an NDA

(f) In the event that licenses from third parties are required by LICENSEE in order to make, have made, use, sell, offer to sell or import any particular Licensed Product or Licensed Process, then the earned royalty which LICENSEE is obligated to pay LICENSOR under this Agreement shall be reduced by [*****] for each one dollar ($1.00) in royalties which Licensee is obligated to pay to third parties under such licenses, further provided, however, that the royalties payable to LICENSOR under this Section shall not be reduced to less than [*****] of the applicable Net Sales.

8.2 All payments shall be made hereunder in U.S. dollars; provided however, that if the proceeds of the sales upon which such royalty payments are based are received by the LICENSEE in a foreign currency or other form that is not convertible or exportable in dollars, and the LICENSEE does not have ongoing business operations or bank accounts in the country in which the currency is not convertible or exportable, the LICENSEE shall pay such royalties in the currency of the country in which such sales were made by depositing such royalties in LICENSOR'S name in a bank designated by LICENSOR in such country. Royalties in dollars shall be computed by converting the royalty in the currency of the country in which the sales were made at the exchange rate for dollars prevailing at the close of the business day of the LICENSEE'S quarter for which royalties are being calculated as published the following day in the Wall Street Journal (or, if it ceases to be published, a comparable publication to be agreed upon from time to time by the parties), and with respect to those countries for which rates are not published in the Wall Street Journal, the exchange rate fixed for such date by the appropriate United States governmental agency.

8.3 In the event the royalties set forth herein are higher than the maximum royalties permitted by the law or regulations of a particular country, the royalty payable for sales in such country shall be equal to the maximum permitted royalty under such law or regulation.

8.4 In the event that any taxes, withholding or otherwise, are levied by any taxing authority in connection with accrual or payment of any royalties payable to

LICENSOR under this Agreement, the LICENSEE shall have the right to pay such taxes to the local tax authorities on behalf of LICENSOR and the payment to LICENSOR of the net amount due after reduction by the amount of such taxes, shall fully satisfy the LICENSEE'S royalty obligations under this Agreement.

8.5 As partial consideration for the license granted pursuant to this Agreement, LICENSEE shall issue to LICENSOR a fully paid, nonassessable number of common shares equal to [*****] of the total number of LICENSEE common shares issued and outstanding. LICENSEE shall affect the issuance of such shares by concurrent execution of an appropriate Stockholders Agreement and Investor Rights Agreements, the terms of which are incorporated by reference herein.

9. DILIGENCE:

9.1 LICENSEE shall use efforts at least sufficient to meet the requirements of the Bayh-Dole Act to manufacture, market and sell the Licensed Products in the Territory, and to create a demand for the Products.

9.2 LICENSEE agrees to submit reports, upon LICENSOR's request but no more than every 6 months as to its efforts to develop markets for the Licensed Products. Such reports shall include assurance by LICENSEE of its intent to actively develop commercial embodiments of Licensed Products and a summary of its efforts in this regard.

9.3 Unless LICENSEE has introduced a Licensed Product into the commercial marketplace in one of the three major markets (European Union, Japan and the United States) or has made best efforts (for avoidance of doubt it will be presumed that LICENSEE has used best efforts if it has a Licensed Product in a phase III clinical trial) to achieve the same prior to December 31, 2020, LICENSEE agrees that LICENSOR may terminate this Agreement by providing LICENSEE ninety (90) advanced written notice of its intent to terminate this Agreement. In the event the payment of earned royalties, once begun and if any are due, ceases for more than two (2) calendar quarters, and LICENSEE fails to cure this breach within two (2) months after being provided written notice of same, LICENSOR may terminate this Agreement.

10. REPORTS AND RECORDS:

10.1 Commencing one (1) year after the first sale, the LICENSEE shall furnish to LICENSOR a report in writing specifying during the preceding calendar quarter (a) the number or amount of Licensed Products sold hereunder by LICENSEE, and/or its Affiliates or Sublicensees, (b) the total billings for all Licensed Products sold, (c) deductions as applicable in paragraph 1.6, (d) total royalties due, (e) names and addresses of all Sublicensees. Such reports shall be due within forty-five (45) days following the last day of each calendar quarter in each year during the term of this Agreement. Each such report shall be accompanied by payment in full of the amount due LICENSOR in United States dollars calculated in accordance with Section 8.1 hereof.

10.2 For a period of three (3) years from the date of each report pursuant to Paragraph 10.1, LICENSEE, shall keep records adequate to verify each such report and accompanying payment made to LICENSOR under this Agreement, and an independent certified public accountant or accounting firm selected by LICENSOR and acceptable to LICENSEE may have access, on reasonable notice during regular business hours, not to exceed once per year, to such records to verify such reports and payments. Such accountant or accounting firm shall not disclose to LICENSOR any information other than that information relating solely to the accuracy of, or necessity for, the reports and payments made hereunder. The fees and expense of the certified public accountant or accounting firm performing such verification shall be borne by LICENSOR unless in the event that the audit reveals an underpayment of royalty by more than [*****], the cost of the audit shall be paid by LICENSEE.

11. MARKING AND STANDARDS:

11.1 Prior to the issuance of patents on the Invention(s), LICENSEE agrees to mark and have sublicensees mark Licensed Products (or their containers or labels) made, sold, or otherwise disposed of by it under the license granted in this Agreement with a proper patent notice as specified under the patent laws of the United States.

11.2 LICENSEE further agrees to maintain satisfactory standards in respect to the nature of the Licensed Products manufactured and/or sold by LICENSEE.

LICENSEE, agrees that all Licensed Products manufactured and/or sold by it shall be of a quality which is appropriate to products of the type here involved. LICENSEE agrees that similar provisions shall be included in sublicenses of all tiers.

12. ASSIGNMENT:

12.1 This Agreement is not assignable by LICENSEE or by operation of law without the prior written consent of LICENSOR at its sole discretion except that LICENSEE shall have the right to transfer or assign this Agreement to any entity which acquires all or substantially all of LICENSEE's assets provided that LICENSEE gives LICENSOR thirty (30) days advance written notice of the intended assignment and considers in good faith any of LICENSOR's concerns relating to the intended assignment. The foregoing sentence shall not be construed to require LICENSEE to obtain LICENSOR's approval of any Sublicensee.

12.2 This Agreement shall extend to and be binding upon the successors and legal representatives and permitted assigns of LICENSOR and LICENSEE.

13. NOTICE:

Any notice, payment, report or other correspondence (hereinafter collectively referred to as "correspondence") required or permitted to be given hereunder shall be mailed by certified mail or delivered by hand to the party to whom such correspondence is required or permitted to be given hereunder. If mailed, any such notice shall be deemed to have been given when mailed as evidenced by the postmark at point of mailing. If delivered by hand, any such correspondence shall be deemed to have been given when received by the party to whom such correspondence is given, as evidenced by written and dated receipt of the receiving party.

All correspondence to LICENSEE shall be addressed as follows:

Mr. Jeffrey Wolf
CEO
Heat Biologics, Inc.
Atlantic Center

119 Washington Avenue, Suite 401
Miami Beach , FL 33139

All correspondence to LICENSOR shall be addressed, in duplicate, as follows:

FOR NOTICE:

Vice President
Business Affairs
327 Max Orovitz Building
1507 Levante Avenue
Coral Gables, Florida 33124-1432
Attention: Mr. Alan J. Fish

FOR NOTICE AND PAYMENT:

UM Innovation
Office of Special Programs and Resource Strategy
1150 NW 14th Street, Suite 310
Miami, FL 33136

Either party may change the address to which correspondence to it is to be addressed by notification as provided herein.

14. TERMINATION:

14.1 A party shall have the right to terminate this Agreement if the other party commits (a) a material breach of an obligation under this Agreement or (b) provides a false report, and continues in breach for more than ninety (90) days after receiving unambiguous written notice of such breach or false report; however, in the event LICENSEE breaches its obligations under Sections five (5) or eight (8) above, LICENSEE shall have thirty (30) days after receiving written notice to cure such breach, after which LICENSOR shall have the right to terminate this Agreement. Such termination shall be

effective upon further written notice to the breaching party after failure by the breaching party to cure such default.

14.2 The license and rights granted in this Agreement have been granted on the basis of the special capability of LICENSEE to perform research and development work leading to the manufacture and marketing of the Products. Accordingly, LICENSEE covenants and agrees that in the event any proceedings under the Bankruptcy Act or any amendment thereto, be commenced by or against LICENSEE, and, if against LICENSEE, said proceedings shall not be dismissed with prejudice before either an adjudication in bankruptcy or the confirmation of a composition, arrangement, or plan of reorganization, or in the event LICENSEE shall be adjudged insolvent or make an assignment for the benefit of its creditors, or if a writ of attachment or execution be levied upon the license hereby created and not be released or satisfied within ten (10) days thereafter, or if a receiver be appointed in any proceeding or action to which LICENSEE is a party with authority to exercise any of the rights or privileges granted hereunder and such receiver be so discharged within a period of forty-five (45) days after his appointment, any such event shall be deemed to constitute a breach of this Agreement by LICENSEE and, LICENSOR, at the election of LICENSOR, but not otherwise, ipso facto, and without notice or other action by LICENSOR, shall terminate this Agreement and all rights of LICENSEE hereunder and all rights of any and all persons claiming under LICENSEE.

14.3 LICENSEE shall have the right to terminate this Agreement by providing ninety (90) days written notice of its intent to terminate this Agreement to LICENSOR.

14.4 Any termination of this Agreement shall be without prejudice to LICENSOR's right to recover all amounts accruing to LICENSOR prior to such termination and cancellation. Except as otherwise provided, should this Agreement be terminated for any reason, LICENSEE shall have no rights, express or implied, under any patent property which is the subject matter of this Agreement, nor have the right to recover any royalties paid LICENSOR hereunder. Upon termination, LICENSEE shall have the right to dispose of Licensed Products then in their possession and to complete existing contracts for such products, so long as contracts are completed within six (6)

months from the date of termination, subject to the payment of royalties to LICENSOR as provided in Section 8 hereof.

15. CERTIFICATE OF INSURANCE:

15.1 At least thirty (30) days before it causes a Licensed Product to be administered to a human subject, LICENSEE shall obtain (and thereafter shall maintain) liability insurance coverage for the Product in the amount of three million dollars ($3,000,000) and at no expense to LICENSOR, LICENSEE shall name LICENSOR as an additional insured. Within fourteen (14) days before it causes a Licensed Product to be administered to a human subject, LICENSEE shall provide a certificate of such product liability insurance to LICENSOR. LICENSEE agrees to carry and keep in force, at its expense, general liability insurance with limits not less than $1,000,000 per person and $3,000,000 aggregate to cover liability for damages on account of bodily or personal injury or death to any person, or damage to property of any person. Such insurance shall contain an endorsement naming the University of Miami as an additional insured with respect to this Agreement. Within fourteen (14) days of the Effective Date, LICENSEE shall provide a certificate of such general liability insurance to LICENSOR. Insurance Certificates should be sent to the University of Miami upon execution of this Agreement and on the anniversary of that date every year thereafter, Office of Technology Transfer, 1475 NW 12th Avenue, Sewell Building Room 2012, Miami, Florida 33136.

15.2 Licensee shall not cancel such insurance without thirty (30) days prior notice to Licensor. Such cancellation shall be cause for termination.

15.3 The terms of this provision shall extend beyond termination of the agreement.

16. USE OF NAME:

LICENSEE shall not use the name of the University of Miami, or any of its employees, or any adaptation thereof, in any publication, including advertising, promotional or sales literature without the prior written consent of Mr. Alan J. Fish, Vice President of Business Services, 327 Max Orovitz Bldg., 1507 Levante Avenue, Coral Gables, FL 33124-1432. LICENSOR shall notify LICENSEE within ten (10) days of

being provided notice of its decision regarding each instance of intended use of name(s) name(s). The absence of a response by LICENSOR within this ten (10) day period shall constitute implied permission for LICENSEE to use such name in that instance. Any press releases concerning this Agreement must be mutually agreed upon by the parties.

17. GOVERNING LAW:

This Agreement shall be governed by and interpreted in accordance with the laws of the State of Florida.

18. CAPTIONS:

The captions and paragraph heading of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

19. SEVERABILITY:

Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provision shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such part or provision in valid and enforceable manner, and the remainder of the Agreement shall remain binding upon the parties hereto.

20. SURVIVAL:

20.1 The provisions of Sections 5, 6 and 7 shall survive the termination or expiration of this Agreement and shall remain in full force and effect.

20.2 The provisions of this Agreement which do not survive termination or expiration hereof (as the case may be) shall, nonetheless, be controlling on, and shall be used in construing and interpreting, the rights and obligations of the parties hereto with regard to any dispute, controversy or claim which may arise under, out of, in connection with, or relating to this Agreement.

21. AMENDMENT:

No amendment or modification of the terms of this Agreement shall be binding on either party unless reduced to writing and signed by an authorized officer of the party to be bound.

22. WAIVER:

No failure or delay on the part of a party in exercising any right hereunder will operate as a waiver of, or impair, any such right. No single or partial exercise of any such right will preclude any other or further exercise thereof or the exercise of any other right. No waiver of any such right will be deemed a waiver of any other right hereunder.

23. CONFIDENTIALITY:

Each Party shall maintain all information of the other Party which is treated by such other Party as proprietary or confidential (referred to herein as "Confidential Information") in confidence, and shall not disclose, divulge or otherwise communicate such confidential information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and each party hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such confidential information by any of its Affiliates, directors, officers, employees, consultants, subcontractors, sublicensees or agents. LICENSEE's Confidential Information includes but is not limited to the development plan, development reports and all other financial and business reports, strategies, and agreements (including sublicenses) of LICENSEE. The parties agree to keep the terms of this Agreement confidential, provided that each party may disclose this Agreement to their authorized agents and investors who are bound by similar confidentiality provisions. Notwithstanding the foregoing, Confidential Information of a party shall not include information which: (a) was lawfully known by the receiving party prior to disclosure of such information by the disclosing party to the receiving party; (b) was or becomes generally available in the public domain, without the fault of the receiving party; (c) is subsequently disclosed to the receiving party by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed, provided that the receiving party making such disclosure shall take all reasonable steps to restrict and maintain to the extent possible confidentiality of such disclosure and shall provide reasonable notice to the other party to allow such party the opportunity to oppose the required disclosure; or (e) has been independently developed by employees

or others on behalf of the receiving party without access to or use of disclosing party's information as demonstrated by written record. Each party's obligations under this Section shall extend for a period of five (5) years from termination or expiration of this Agreement.

24. UNIVERSITY RULES AND REGULATIONS:

LICENSEE understands and agrees that University of Miami personnel who are engaged by LICENSEE, whether as consultants, employees or otherwise, or who possess a material financial interest in LICENSEE, are subject to the University of Miami's rule regarding outside activities and financial interests, and the University of Miami's Intellectual Property Policy. Any term or condition of an agreement between LICENSEE and such University of Miami personnel which seeks to vary or override such personnel's obligations to the University of Miami may not be enforced against such personnel, or the University of Miami, without the express written consent of an individual authorized to vary or waive such obligations on behalf of the University of Miami.

25. ENTIRE AGREEMENT:

This Agreement constitutes the entire agreement between the parties hereto respecting the subject matter hereof, and supersedes and terminates all prior agreements respecting the subject matter hereof, whether written or oral, and may be amended only by an instrument in writing executed by both parties hereto.

26. CONTRACT FORMATION AND AUTHORITY:

LICENSOR and LICENSEE each warrant and represent that the persons signing this Agreement on its behalf have authority to execute this Agreement and that the execution of this Agreement does not violate any law, rule or regulation applicable to it or any contract or other agreement by which it is bound.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective officers thereunto duly authorized to be effective as of the Effective Date.

[SIGNATURE PAGE FOLLOWS]

HEAT BIOLOGICS II, INC.

Date: July 11, 2008

By: /s/ Jeffrey Wolf

Jeffrey Wolf
Name

CEO
Title

UNIVERSITY OF MIAMI

Date:_____

By: /s/ Bart Chernow

Bart Chernow
Name

Vice President
Title

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS EXHIBIT MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

LICENSE AGREEMENT

This License Agreement (the "Agreement") is entered into and made effective the 12th day of December, 2010 (the "Effective Date") between UNIVERSITY OF MIAMI and its School of Medicine, whose principal place of business is at 1600 N.W. 10th Avenue, Miami, Florida 33136 (hereinafter referred to as "LICENSOR") and HEAT BIOLOGICS II, INC., a Delaware corporation, whose principal place of business is at Atlantic Center, 119 Washington Avenue, Suite 401, Miami Beach, FL 33139 (hereinafter referred to as "LICENSEE").

WITNESSETH

WHEREAS, HEAT BIOLOGICS, Inc., a Delaware Corporation ("HEAT") is the majority shareholder of the LICENSEE. With effect of July 11, 2008, HEAT and the LICENSOR have entered into a license agreement regarding the Podack Antibody Technology (UM03-31 and UM05-39) which was later assigned to the LICENSEE (hereinafter also referred to herein as the "Podack Antibody License Agreement");

WHEREAS, LICENSOR is the sole owner of the technology and product identified as the Treg Expansion (UMI176) technology;

WHEREAS, LICENSOR is the sole owner of the patent rights relating to the Treg Expansion (UMI176) technology;

WHEREAS, LICENSOR wishes to exclusively license to LICENSEE the Treg Expansion (UMI176) technology and patent rights related thereto; and

WHEREAS, LICENSEE desires to acquire an exclusive license from LICENSOR to the Treg Expansion (UMI176) technology and patent rights related thereto for the purpose of commercially marketing the Treg Expansion (UMI176) technology.

NOW THEREFORE, For these and other valuable considerations, the receipt of which is hereby acknowledged, the parties agree as follows:

1. DEFINITIONS:

1.1 "Affiliate" shall mean any corporation or other business entity controlled by, controlling or under common control with LICENSEE. For this purpose, "control" shall mean direct or indirect beneficial ownership of at least a fifty percent (50%) of the voting stock of, or at least a fifty percent (50%) interest in the income of such corporation or other business entity, or such other relationship as in fact, constitutes actual control.

1.2 "Sublicensee" as used in this Agreement shall mean any third party to whom LICENSEE has granted a license to make, have made, use and/or sell the Product under the Patent Rights, provided said third party has agreed in writing with LICENSEE to accept the conditions and restrictions agreed to by LICENSEE in this Agreement.

1.3 "Patent Rights" shall mean the following United States Patent applications: U.S. patent application serial number US 61/273,299 entitled "Method for In Vivo Expansion of T Regulatory Cells" and filed on 3 August 2009; PCT application number PCT/US10/44218 entitled "Method for In Vivo Expansion of T Regulatory Cells" and filed on 3 August 2010; all United States patents and foreign patents and patent applications based on these patent applications; all divisionals, continuations of the foregoing; and those claims in continuations-in-part of the foregoing that are described in sufficient detail in U.S. patent application serial number US 61/273,299, or PCT application number PCT/US10/44218 to meet the requirements of 35 U.S.C. 112¶1; and any re-examinations or reissues of the foregoing.

1.4 "Licensed Product" shall mean any product or part thereof which:

(a) is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights;

(b) is manufactured by using a process which is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights; or

(c) incorporates or comprises the Licensed Materials.

1.5 "Licensed Process" shall mean any process practiced in a country in which said process is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or pending claim contained in the Patent Rights.

1.6 "Net Sales" shall mean the sum of all amounts invoiced on account of sale or use of Licensed Products and Licensed Processes by LICENSEE and its Affiliates or any Sublicensees to non-affiliated third party purchasers or users of Licensed Products or Licensed Processes, less (a) discounts to purchasers in amounts customary in the trade, (b) amounts for transportation or shipping charges to purchasers, (c) credits for returns, allowances or trades, and (d) taxes and duties levied on the sale or use of Licensed Products, whether absorbed by Licensee or paid by the purchaser.

1.7 "Territory" shall mean worldwide.

1.8 "Field of Use" shall mean all human healthcare and research applications.

1.9 The "Treg Expansion (UMI176)" technology shall mean the technology described in Patent Rights.

1.10 "Licensed Materials" shall mean LICENSOR's biological materials in the possession of Dr. Eckhard Podack's laboratory at the Effective Date that are covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights.

1.11 "LICENSEE Materials" shall mean any biological materials (e.g., humanized monoclonal antibodies) that LICENSEE makes or has made using Licensed Materials or sequence information from any polynucleotides or polypeptides contained in the Licensed Materials.

2. GRANT:

2.1 LICENSOR hereby grants to LICENSEE an exclusive license, subject to any rights of the U.S. government specified in section 4 below, in the Territory for the Field of Use, with the right to sublicense, under the Patent Rights, to make, have made for its own use and sale, use and sell Licensed Products and Licensed Processes.

2.2 LICENSOR also hereby grants to LICENSEE an exclusive license to make, use, and/or sell the Licensed Materials in the Territory for the Field of Use. At LICENSEE's request, LICENSOR shall provide LICENSEE with a reasonable amount of Licensed Materials so that LICENSEE may reproduce such Licensed Materials for the purpose of making, selling, or using Licensed Products or Licensed Processes.

2.3 LICENSOR reserves to itself the non-transferable right to make and use Licensed Materials, Licensed Products and/or Licensed Processes solely for its internal, non-commercial: scientific research, not-for-profit clinical research, and educational purposes. Except to the extent required by law, LICENSOR shall not transfer the Licensed Materials for the purpose of making the Licensed Materials to any third party without first obtaining, in a Material Transfer Agreement, the written agreement of that third party to not use or further distribute such materials for commercial purposes. LICENSOR shall notify LICENSEE in writing of any third party request for such materials and provide LICENSEE at least ten (10) days to object to such request on the basis that such transfer would interfere with the objectives of this Agreement.

2.4 LICENSEE hereby grants to LICENSOR the non-transferable right to make and use LICENSEE Materials solely for its internal, non-commercial scientific research, not-for-profit clinical research, and educational purposes. At LICENSOR's request, LICENSEE shall provide LICENSOR with a reasonable amount of LICENSEE Materials solely for the aforesaid purpose. Without the express written consent of LICENSEE, LICENSOR shall not transfer to a third party any LICENSEE Materials or derivatives thereof or any non-public sequence information from any polynucleotides or polypeptides contained in the foregoing.

3. TERM:

The license granted by this Agreement shall be exclusive in the licensed Field of Use for a term commencing as of the Effective Date of this Agreement and continue until the expiration, on a country by country basis, of all of the Patent Rights.

4. **UNITED STATES LAWS:**

4.1 Licensee understands that the Licensed Subject Matter may have been developed under a funding agreement with the Government of the United States of America and, if so, that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to the Government's rights under any agreement and any applicable law or regulation. If there is a conflict between an agreement, applicable law or regulation and this Agreement, the terms of the Government agreement, applicable law or regulation shall prevail.

Specifically, This Agreement is subject to all of the terms and conditions of Title 35 United States Code sections 200 through 204, including an obligation that Licensed Product(s) sold or produced in the United States be "manufactured substantially in the United States," and LICENSEE agrees to take all reasonable action necessary on its part as licensee to enable LICENSOR to satisfy its obligation thereunder, relating to Invention(s).

4.2 It is understood that LICENSOR is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the Export Administration Act of 1979), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by LICENSEE that LICENSEE shall not export data or commodities to certain foreign countries without prior approval of such agency. LICENSOR neither represents that a license shall not be required nor that, if required, it shall be issued.

5. PATENT PROTECTION AND INFRINGEMENT:

5.1 LICENSOR, during the term of this Agreement, is responsible for the filing and the prosecution of all patents and applications where LICENSEE shall reimburse LICENSOR for all payments within thirty (30) days of invoice. LICENSOR shall keep LICENSEE fully apprised on the status of all Patent Rights and shall provide LICENSEE the opportunity to make comments and suggestions on all decisions relating to

the prosecution of the Patent Rights (e.g., office actions). LICENSOR shall in good faith consider incorporating such comments and suggestions unless such incorporation would be contrary to the purposes of this Agreement.

5.2 LICENSEE shall promptly notify LICENSOR in writing of any claim of Patent Rights infringement which may be asserted against LICENSEE or LICENSOR, its Affiliates and any sublicensees because of the manufacture, use, promotion and sale of Products.

5.3 LICENSEE shall pay to LICENSOR a license issue fee in the amount of [$50,000] and past patent fees in an amount of [$15,796.58] incurred as of 10/22/2010 within thirty (30) days of the Effective Date. LICENSEE shall also pay to LICENSOR all future patent fees within thirty (30) days after the LICENSEE has received the invoice from LICENSOR pertaining to such future patent fee.

5.4 LICENSEE will defend, indemnify and hold harmless LICENSOR, its trustees, officers, directors, employees and its Affiliates against any and all judgments and damages arising from any and all third party claims of Patent Rights infringement which may be asserted against LICENSOR, and Affiliates because of the manufacture, use, promotion and sale of Licensed Products except for the use of Licensed Materials, Licensed Products and/or Licensed Processes by Licensor pursuant to section 2.3 of this Agreement. LICENSEE will bear all costs and expenses incurred in connection with the defense of any such claims or as a result of any settlement made or judgment rendered on the basis of such claims. LICENSOR shall have no further liability to LICENSEE for any loss or damages LICENSEE may incur as a result of the invalidity of LICENSOR'S Patent Rights. LICENSOR will have the right, but not the obligation to retain counsel at its expense in connection with any such claim. LICENSOR at its option, shall have the right, within thirty days after commencement of such action, to intervene and take over the sole defense of the action at its own expense.

5.5 Upon learning of any infringement of Patent Rights by third parties in any country, LICENSEE and LICENSOR will promptly inform each other, as the case may be, in writing of that fact and will supply the other with any available evidence pertaining to the infringement. LICENSEE at its own expense, shall have the option to

take whatever steps are necessary to stop the infringement at its expense and recover damages therefore. If requested by LICENSEE, LICENSOR will join in any legal actions enforcing or defending the Patent Rights against third parties deemed necessary or advisable by LICENSEE to prevent or seek damages, or both, from the infringement of the Patent Rights provided that LICENSEE funds all costs associated with such actions, using counsel mutually acceptable to LICENSEE and LICENSOR, and indemnifies and holds LICENSOR harmless with respect to any claims or damages made against or sustained by LICENSOR in connection with such involvement. In the event that LICENSOR and LICENSEE mutually bring suit, costs and expenses shall be borne by LICENSEE, and any recovery shall be shared by the parties as if such infringing sales were Net Sales. In any event, no settlement, consent, judgment or other voluntary final disposition of the suit may be entered into without the consent of LICENSOR, which shall not be unreasonably withheld. In the event LICENSEE does not take steps to stop the infringement, LICENSOR shall have the right to bring suit at its own expense. In such event, financial recoveries will be entirely retained by LICENSOR.

5.6 LICENSOR shall have no responsibility with respect to LICENSEE'S own trademarks and trade name, and LICENSEE in respect to the use thereof will defend, indemnify and hold harmless LICENSOR against any and all third party claims.

6. INDEMNIFICATION:

6.1 LICENSEE agrees to release, indemnify and hold harmless the LICENSOR, its trustees, officers, faculty, employees and students against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including reasonable attorney's fees through the appellate levels) which may be brought against LICENSOR, its trustees, officers, faculty, employees or students as a result of or arising out of any negligent act or omission of LICENSEE, its agents, or employees, or arising out of use, production, manufacture, sale, lease, consumption or advertisement by LICENSEE or any Sublicensee of any Licensed Product, Licensed Process, or Licensed Materials covered by this Agreement.

6.2 LICENSOR agrees to release, indemnify and hold harmless the LICENSEE, its directors, officers, employees, Affiliates, Sublicensees, and agents against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including reasonable attorney's fees through the appellate levels) which may be brought against LICENSEE, its directors, officers, employees, Affiliates, Sublicensees, and/or agents as a result of or arising out of any willful misconduct, or negligent act or omission of LICENSOR; or, except where caused by LICENSEE's negligence or willful misconduct, arising out of use, sale, lease, consumption or advertisement by LICENSOR of any LICENSEE Materials covered by this Agreement.

6.3 This Agreement to reimburse and indemnify under the circumstances set forth above shall continue after the termination of this Agreement.

7. REPRESENTATIONS/WARRANTIES:

7.1 LICENSOR hereby represents and warrants to LICENSEE that LICENSOR owns the Patent Rights and Licensed Materials and has not assigned any rights therein or given any license or other rights thereto to any party other than LICENSEE.

7.2 LICENSOR hereby represents and warrants that, although it has not conducted any investigation, it has no knowledge of any patents or patent applications, other than the Patents Rights, that contain a claim that would be infringed by the sale or use of a Licensed Product, Licensed Process, or Licensed Materials.

7.3 EXCEPT AS PROVIDED ABOVE, LICENSOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AND HEREBY DISCLAIMS ALL SUCH WARRANTIES, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE CONDITION OF ANY INVENTION(S) OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, LICENSED UNDER THIS AGREEMENT; OR THE MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE INVENTION OR PRODUCT; OR THAT THE USE OF THE LICENSED PRODUCT WILL NOT INFRINGE ANY PATENT, COPYRIGHTS, TRADEMARKS, OR OTHER RIGHTS. OTHER THAN FOR BREACH OF THE ABOVE

WARRANTIES, OR ITS OWN NEGLIGENT ACTS OR OMISSIONS, LICENSOR SHALL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY ANY LICENSEE OR ANY THIRD PARTIES RESULTING FROM THE USE, PRODUCTION, MANUFACTURE, SALE, LEASE, CONSUMPTION, OR ADVERTISEMENT OF THE PRODUCT.

7.4 EXCEPT EXPLICITLY PROVIDED FOR HEREIN, LICENSEE DOES NOT MAKE ANY OTHER REPRESENTATIONS OR GIVE ANY OTHER EXPLICIT OR IMPLICIT WARRANTIES. TO THE FULLEST EXTENT PERMITTED BY LAW LICENSEE HEREBY DISCLAIMS ANY OTHER REPRESENTATIONS AND WARRANTIES.

7.5 The provisions of this Section shall continue beyond the termination of this Agreement.

8. ROYALTIES:

8.1 In consideration of the license herein granted, LICENSEE shall pay royalties to LICENSOR as follows:

(a) LICENSEE agrees to pay to LICENSOR a license issue fee of [$15,796.58] and past patent fees in an amount of [*****] as of October 22, 2010 within thirty (30) days of the Effective Date.

(b) LICENSEE agrees to pay LICENSOR minimum royalty payments, as follows:

Payment	Year
[$10,000]	2012
[$10,000]	2013
[$10,000]	2014
[$20,000]	2015 and every year thereafter on the same date, for the life of this Agreement.

The minimum royalty shall be paid for each year in which this Agreement is in effect. The minimum royalty payment shall be due on or before December 31 of the calendar year. Any minimum royalty paid in a calendar year will be credited against the earned royalties for that calendar year. It is understood that the minimum royalties will be applied to earned royalties on a calendar year basis, and that sales of Licensed Products and/or Licensed Processes requiring the payment of earned royalties made during a prior or subsequent calendar year shall have no effect on the annual minimum royalty due LICENSOR for other than the same calendar year in which the royalties were earned.

(c) LICENSEE agrees to pay to LICENSOR as earned royalties a royalty calculated as a percentage of LICENSEE's Net Sales of Licensed Products which, if not for this Agreement, would infringe the Patent Rights, in accordance with the terms and conditions of this Agreement. The royalty is deemed earned as of the earlier of the date the Licensed Product and/or Licensed Process is actually sold and paid for, the date an invoice is sent by LICENSEE, or the date a Licensed Product and/or Licensed Process is transferred to a third party for any promotional reasons. The royalty shall remain fixed while this Agreement is in effect at a rate of [*****] of Net Sales.

(d) For a sublicense, LICENSEE shall pay to LICENSOR an amount equal to [*****]of what LICENSEE would have been required to pay to LICENSOR had LICENSEE sold the amount of Licensed Products sold by the Sublicensee. In addition, if LICENSEE receives any fees, minimum royalties, or other payments in

consideration for any rights granted under a Sublicense, and such payments are not based directly upon the amount or value of Licensed Products or Licensed Processes sold by the Sublicensee nor represent payment of costs to LICENSEE for a development program which LICENSEE is obligated to perform under such sublicense,, then LICENSEE shall pay LICENSOR [*****] of such payments.

(e) In addition to all other payments required under this Agreement, LICENSEE agrees to pay LICENSOR milestone payments, as follows:

Payment	Event
[$25,000]	Upon submission of an IND
[$25,000]	Upon approval of an IND
[$100,000]	Upon completion of a phase 1 clinical trial
[$500,000]	By the earlier of May 31, 2022 or the approval of an NDA

(f) In the event that licenses from third parties are required by LICENSEE in order to make, have made, use, sell, offer to sell or import any particular Licensed Product or Licensed Process, then the earned royalty which LICENSEE is obligated to pay LICENSOR under this Agreement shall be reduced by [*****] for each one dollar ($1.00) in royalties which Licensee is obligated to pay to third parties under such licenses, further provided, however,

that the royalties payable to LICENSOR under this Section shall not be reduced to less than [*****]of the applicable Net Sales.

(g) In the event that LICENSEE requires more than one license from the LICENSOR to make, have made for its use, sell, offer to sell or import any particular Licensed Product or Licensed Process as defined in sections 1.5 and 1.6, respectively, of this Agreement, then the combined earned royalties shall not exceed [*****]of Net Sales and any sublicense fees shall not exceed [*****] of what LICENSEE would have been required to pay to LICENSOR had LICENSEE sold the amount of Licensed Products sold by the Sublicensee.

8.2 All payments shall be made hereunder in U.S. dollars; provided however, that if the proceeds of the sales upon which such royalty payments are based are received by the LICENSEE in a foreign currency or other form that is not convertible or exportable in dollars, and the LICENSEE does not have ongoing business operations or bank accounts in the country in which the currency is not convertible or exportable, the LICENSEE shall pay such royalties in the currency of the country in which such sales were made by depositing such royalties in LICENSOR'S name in a bank designated by LICENSOR in such country. Royalties in U.S. dollars shall be computed by converting the royalty in the currency of the country in which the sales were made at the exchange rate for U.S. dollars prevailing at the close of the business day of the LICENSEE'S quarter for which royalties are being calculated as published the following day in the Wall Street Journal (or, if it ceases to be published, a comparable publication to be agreed upon from time to time by the parties), and with respect to those countries for which rates are not published in the Wall Street Journal, the exchange rate fixed for such date by the appropriate United States governmental agency.

8.3 In the event the royalties set forth herein are higher than the maximum royalties permitted by the law or regulations of a particular country, the royalty

payable for sales in such country shall be equal to the maximum permitted royalty under such law or regulation.

8.4 In the event that any taxes, withholding or otherwise, are levied by any taxing authority in connection with accrual or payment of any royalties payable to LICENSOR under this Agreement, the LICENSEE shall have the right to pay such taxes to the local tax authorities on behalf of LICENSOR and the payment to LICENSOR of the net amount due after reduction by the amount of such taxes, shall fully satisfy the LICENSEE'S royalty obligations under this Agreement.

9. DILIGENCE:

9.1 LICENSEE shall use efforts at least sufficient to meet the requirements of the Bayh-Dole Act to manufacture, market and sell the Licensed Products in the Territory, and to create a demand for the Products.

9.2 LICENSEE agrees to submit reports, upon LICENSOR's request but no more than every 6 months as to its efforts to develop markets for the Licensed Products. Such reports shall include assurance by LICENSEE of its intent to actively develop commercial embodiments of Licensed Products and a summary of its efforts in this regard.

9.3 Unless LICENSEE has introduced a Licensed Product into the commercial marketplace in one of the three major markets (European Union, Japan and the United States) or has made best efforts (for avoidance of doubt it will be presumed that LICENSEE has used best efforts if it has a Licensed Product in a phase III clinical trial) to achieve the same prior to December 31, 2020, LICENSEE agrees that LICENSOR may terminate this Agreement by providing LICENSEE ninety (90) advanced written notice of its intent to terminate this Agreement. In the event the payment of earned royalties, once begun and if any are due, ceases for more than two (2) calendar quarters, and LICENSEE fails to cure this breach within two (2) months after being provided written notice of same, LICENSOR may terminate this Agreement.

10. REPORTS AND RECORDS:

10.1 Commencing one (1) year after the first sale, the LICENSEE shall furnish to LICENSOR a report in writing specifying during the preceding calendar quarter (a) the number or amount of Licensed Products sold hereunder by LICENSEE, and/or its Affiliates or Sublicensees, (b) the total billings for all Licensed Products sold, (c) deductions as applicable in paragraph 1.6, (d) total royalties due, (e) names and addresses of all Sublicensees. Such reports shall be due within forty-five (45) days following the last day of each calendar quarter in each year during the term of this Agreement. Each such report shall be accompanied by payment in full of the amount due LICENSOR in United States dollars calculated in accordance with Section 8.1 hereof.

10.2 For a period of three (3) years from the date of each report pursuant to Paragraph 10.1, LICENSEE, shall keep records adequate to verify each such report and accompanying payment made to LICENSOR under this Agreement, and an independent certified public accountant or accounting firm selected by LICENSOR and acceptable to LICENSEE may have access, on reasonable notice during regular business hours, not to exceed once per year, to such records to verify such reports and payments. Such accountant or accounting firm shall not disclose to LICENSOR any information other than that information relating solely to the accuracy of, or necessity for, the reports and payments made hereunder. The fees and expense of the certified public accountant or accounting firm performing such verification shall be borne by LICENSOR unless in the event that the audit reveals an underpayment of royalty by more than [*****] percent, the cost of the audit shall be paid by LICENSEE.

11. MARKING AND STANDARDS:

11.1 LICENSEE agrees to mark and have sublicensees mark Licensed Products (or their containers or labels) made, sold, or otherwise disposed of by it under the license granted in this Agreement with a proper patent notice as specified under the patent laws of the United States.

11.2 LICENSEE further agrees to maintain satisfactory standards in respect to the nature of the Licensed Products manufactured and/or sold by LICENSEE.

LICENSEE, agrees that all Licensed Products manufactured and/or sold by it shall be of a quality which is appropriate to products of the type here involved. LICENSEE agrees that similar provisions shall be included in sublicenses of all tiers.

12. ASSIGNMENT:

12.1 This Agreement is not assignable by LICENSEE or by operation of law without the prior written consent of LICENSOR at its sole discretion except that LICENSEE shall have the right to transfer or assign this Agreement to any entity which acquires all or substantially all of LICENSEE's assets provided that LICENSEE gives LICENSOR thirty (30) days advance written notice of the intended assignment and considers in good faith any of LICENSOR's concerns relating to the intended assignment. The foregoing sentence shall not be construed to require LICENSEE to obtain LICENSOR's approval of any Sublicensee.

12.2 This Agreement shall extend to and be binding upon the successors and legal representatives and permitted assigns of LICENSOR and LICENSEE.

13. NOTICE:

Any notice, payment, report or other correspondence (hereinafter collectively referred to as "correspondence") required or permitted to be given hereunder shall be mailed by certified mail or delivered by hand to the party to whom such correspondence is required or permitted to be given hereunder. If mailed, any such notice shall be deemed to have been given when mailed as evidenced by the postmark at point of mailing. If delivered by hand, any such correspondence shall be deemed to have been given when received by the party to whom such correspondence is given, as evidenced by written and dated receipt of the receiving party.

All correspondence to LICENSEE shall be addressed as follows:

Mr. Jeffrey Wolf

CEO

Heat Biologics, Inc.

Atlantic Center
119 Washington Avenue, Suite 401
Miami Beach , FL 33139

All correspondence to LICENSOR shall be addressed, in duplicate, as follows:

FOR NOTICE:

Assistant Vice President
Treasurer
327 Max Orovitz Building
1507 Levante Avenue
Coral Gables, Florida 33124-1432
Attention: Mr. Humberto Speziani

FOR NOTICE AND PAYMENT:

Office of Technology Transfer
P.O. Box 016960 (M811)
Miami, FL 33101

Either party may change the address to which correspondence to it is to be addressed by notification as provided herein.

14. TERMINATION:

14.1 A party shall have the right to terminate this Agreement if the other party commits (a) a material breach of an obligation under this Agreement or (b) provides a false report, and continues in breach for more than ninety (90) days after receiving unambiguous written notice of such breach or false report; however, in the event LICENSEE breaches its obligations under Sections five (5) or eight (8) above, LICENSEE shall have thirty (30) days after receiving written notice to cure such breach, after which

LICENSOR shall have the right to terminate this Agreement. Such termination shall be effective upon further written notice to the breaching party after failure by the breaching party to cure such default.

14.2 The license and rights granted in this Agreement have been granted on the basis of the special capability of LICENSEE to perform research and development work leading to the manufacture and marketing of the Products. Accordingly, LICENSEE covenants and agrees that in the event any proceedings under the Bankruptcy Act or any amendment thereto, be commenced by or against LICENSEE, and, if against LICENSEE, said proceedings shall not be dismissed with prejudice before either an adjudication in bankruptcy or the confirmation of a composition, arrangement, or plan of reorganization, or in the event LICENSEE shall be adjudged insolvent or make an assignment for the benefit of its creditors, or if a writ of attachment or execution be levied upon the license hereby created and not be released or satisfied within ten (10) days thereafter, or if a receiver be appointed in any proceeding or action to which LICENSEE is a party with authority to exercise any of the rights or privileges granted hereunder and such receiver be so discharged within a period of forty-five (45) days after his appointment, any such event shall be deemed to constitute a breach of this Agreement by LICENSEE and, LICENSOR, at the election of LICENSOR, but not otherwise, ipso facto, and without notice or other action by LICENSOR, shall terminate this Agreement and all rights of LICENSEE hereunder and all rights of any and all persons claiming under LICENSEE.

14.3 LICENSEE shall have the right to terminate this Agreement by providing ninety (90) days written notice of its intent to terminate this Agreement to LICENSOR.

14.4 Any termination of this Agreement shall be without prejudice to LICENSOR's right to recover all amounts accruing to LICENSOR prior to such termination and cancellation. Except as otherwise provided, should this Agreement be terminated for any reason, LICENSEE shall have no rights, express or implied, under any patent property which is the subject matter of this Agreement, nor have the right to recover any royalties paid LICENSOR hereunder. Upon termination, LICENSEE shall have the right to dispose of Licensed Products then in their possession and to complete

existing contracts for such products, so long as contracts are completed within six (6) months from the date of termination, subject to the payment of royalties to LICENSOR as provided in Section 8 hereof.

15. CERTIFICATE OF INSURANCE:

15.1 At least thirty (30) days before it causes a Licensed Product to be administered to a human subject, LICENSEE shall obtain (and thereafter shall maintain) liability insurance coverage for the Product in the amount of three million dollars ($3,000,000) and at no expense to LICENSOR, LICENSEE shall name LICENSOR as an additional insured. Within fourteen (14) days before it causes a Licensed Product to be administered to a human subject, LICENSEE shall provide a certificate of such product liability insurance to LICENSOR. LICENSEE agrees to carry and keep in force, at its expense, general liability insurance with limits not less than $1,000,000 per person and $3,000,000 aggregate to cover liability for damages on account of bodily or personal injury or death to any person, or damage to property of any person. Such insurance shall contain an endorsement naming the University of Miami as an additional insured with respect to this Agreement. Within fourteen (14) days of the Effective Date, LICENSEE shall provide a certificate of such general liability insurance to LICENSOR. Insurance Certificates should be sent to the University of Miami upon execution of this Agreement and on the anniversary of that date every year thereafter, Office of Technology Transfer, 1475 NW 12th Avenue, Sewell Building Room 2012, Miami, Florida 33136.

15.2 Licensee shall not cancel such insurance without thirty (30) days prior notice to Licensor. Such cancellation shall be cause for termination.

15.3 The terms of this provision shall extend beyond termination of the agreement.

16. USE OF NAME:

LICENSEE shall not use the name of the University of Miami, or any of its employees, or any adaptation thereof, in any publication, including advertising, promotional or sales literature without the prior written consent of Mr. Humberto

Speziani, Assistant Vice President, 327 Max Orovitz Bldg., 1507 Levante Avenue, Coral Gables, FL 33124-1432. LICENSOR shall notify LICENSEE within ten (10) days of being provided notice of its decision regarding each instance of intended use of name(s) name(s). The absence of a response by LICENSOR within this ten (10) day period shall constitute implied permission for LICENSEE to use such name in that instance. Any press releases concerning this Agreement must be mutually agreed upon by the parties.

17. GOVERNING LAW:

This Agreement shall be governed by and interpreted in accordance with the laws of the State of Florida. Any dispute arising out of this Agreement shall be heard in a court of competent jurisdiction located in Miami-Dade County, Florida.

18. CAPTIONS:

The captions and paragraph heading of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

19. SEVERABILITY:

Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provision shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such part or provision in valid and enforceable manner, and the remainder of the Agreement shall remain binding upon the parties hereto.

20. SURVIVAL:

20.1 The provisions of Sections 5, 6 and 7 shall survive the termination or expiration of this Agreement and shall remain in full force and effect.

20.2 The provisions of this Agreement which do not survive termination or expiration hereof (as the case may be) shall, nonetheless, be controlling on, and shall be used in construing and interpreting, the rights and obligations of the parties hereto with

regard to any dispute, controversy or claim which may arise under, out of, in connection with, or relating to this Agreement.

21. AMENDMENT:

No amendment or modification of the terms of this Agreement shall be binding on either party unless reduced to writing and signed by an authorized officer of the party to be bound.

22. WAIVER:

No failure or delay on the part of a party in exercising any right hereunder will operate as a waiver of, or impair, any such right. No single or partial exercise of any such right will preclude any other or further exercise thereof or the exercise of any other right. No waiver of any such right will be deemed a waiver of any other right hereunder.

23. CONFIDENTIALITY:

Each Party shall maintain all information of the other Party which is treated by such other Party as proprietary or confidential (referred to herein as "Confidential Information") in confidence, and shall not disclose, divulge or otherwise communicate such confidential information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and each party hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such confidential information by any of its Affiliates, directors, officers, employees, consultants, subcontractors, sublicensees or agents. LICENSEE's Confidential Information includes but is not limited to the development plan, development reports and all other financial and business reports, strategies, and agreements (including sublicenses) of LICENSEE. The parties agree to keep the terms of this Agreement confidential, provided that each party may disclose this Agreement to their authorized agents and investors who are bound by similar confidentiality provisions. Notwithstanding the foregoing, Confidential Information of a party shall not include information which: (a) was lawfully known by the receiving party prior to disclosure of such information by the disclosing party to the receiving party; (b) was or becomes generally available in the public domain, without the fault of the receiving party; (c) is subsequently disclosed to the

receiving party by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed, provided that the receiving party making such disclosure shall take all reasonable steps to restrict and maintain to the extent possible confidentiality of such disclosure and shall provide reasonable notice to the other party to allow such party the opportunity to oppose the required disclosure; or (e) has been independently developed by employees or others on behalf of the receiving party without access to or use of disclosing party's information as demonstrated by written record. Each party's obligations under this Section shall extend for a period of five (5) years from termination or expiration of this Agreement.

24. UNIVERSITY RULES AND REGULATIONS:

LICENSEE understands and agrees that University of Miami personnel who are engaged by LICENSEE, whether as consultants, employees or otherwise, or who possess a material financial interest in LICENSEE, are subject to the University of Miami's rule regarding outside activities and financial interests, and the University of Miami's Intellectual Property Policy. Any term or condition of an agreement between LICENSEE and such University of Miami personnel which seeks to vary or override such personnel's obligations to the University of Miami may not be enforced against such personnel, or the University of Miami, without the express written consent of an individual authorized to vary or waive such obligations on behalf of the University of Miami.

25. ENTIRE AGREEMENT:

This Agreement constitutes the entire agreement between the parties hereto respecting the subject matter hereof, and supersedes and terminates all prior agreements respecting the subject matter hereof, whether written or oral, and may be amended only by an instrument in writing executed by both parties hereto.

26. CONTRACT FORMATION AND AUTHORITY:

LICENSOR and LICENSEE each warrant and represent that the persons signing this Agreement on its behalf have authority to execute this Agreement and that the execution of this Agreement does not violate any law, rule or regulation applicable to it or any contract or other agreement by which it is bound.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective officers thereunto duly authorized to be effective as of the Effective Date.

[SIGNATURE PAGE FOLLOWS]

HEAT BIOLOGICS II, INC.

Date: 12/08/10

By: /s/ Jeffrey Wolf

Jeffrey Wolf
Name

CEO
Title

UNIVERSITY OF MIAMI

Date: 12/07/10

By: /s/ Humberto Speziani

Humberto Speziani
Name

Assistant Vice President
Title

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS EXHIBIT MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

AMENDMENT TO LICENSE AGREEMENT
(UM03-31, UMO5-39)

Amendment to the License Agreement (the "Amendment") dated the 11th day of July, 2008 (the "Effective Date"). by and between the University of Miami and its School of Medicine ("LICENSOR"), and HEAT BIOLOGICS, INC. a Delaware corporation ("LICENSEE"), under the direction of Dr. Eckhard Podack, to wit: LICENSE AGREEMENT relating to the technology and product identified as the Podack Antibody Technology (**UM03-31, UMO5-39**) and hereinafter referred to as "License Agreement",

WHEREAS, LICENSOR and LICENSEE entered into that certain Stockholders Agreement dated the 11 th day of July. 2008, granting to the LICENSOR certain rights to participate in future stock offerings by the LICENSEE (hereinafter referred to as the "Stockholders Agreement"); and

WHEREAS, LICENSOR is the owner and holder of [*****] of all issued and outstanding common stock of LICENSEE in each class and series on a fully-diluted basis pursuant to the terms and conditions of the License Agreement; together with the University of Miami Investor Rights Agreement effective July 11, 2008, and the Common Stock Subscription Agreement dated July 1, 2008; and

WHEREAS, LICENSEE has license issue fee obligations to LICENSOR, as set forth in sections 5.3 and 8.1(a) of the License Agreement in the total amount of [*****] dollars, which are due and payable as follows:

a) [*****] dollars obligation past due and outstanding, to wit: Payable within thirty (30) days of the Effective Date, on or before August 11, 2008.
b) [*****] dollars paid within one (1) year of the Effective Date;
and

WHEREAS, LICENSEE has past due and outstanding patent fees and costs obligations to LICENSOR in the amount of [*****] dollars pursuant to section 5.1 of the License Agreement; and

WHEREAS, LICENSEE has past due and outstanding license issue fees obligations together with past due and outstanding patent fees and costs obligations to LICENSOR pursuant to the License Agreement in the total amount of [*****] dollars; and

WHEREAS. LICENSEE has requested an extension of the payment dates for past due and future license issue fees together with past due patent fees and costs, and LICENSOR desires to extend the foregoing payment dates.

NOW THEREFORE. for the mutual promises and other good and valuable consideration contained herein, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

LICENSOR agrees to extend the payment dates of the foregoing past due and future license issue fees together with past due patent fees and costs owed by LICENSEE pursuant to the License Agreement, under the following terms and conditions:

1. LICENSOR shall extend the payment deadline of all past due and future license issue fees and past due patent fees and costs under the License Agreement in the total amount of [*****] dollars to August 11, 2009 (the "Extension Date")

2. LICENSOR shall be issued [*****] fully-dilutable common shares of the total number of LICENSEE common shares issued and outstanding, which stock issuance shall be evidenced as

follows:

Section 8.5 of the License Agreement is hereby amended and restated in its entirety to read as follows:

As partial consideration for the license granted pursuant to this Agreement. LICENSEE shall issue to LICENSOR a fully paid, nonassessable number of common shares equal to [*****] of the total number of LICENSEE issued and outstanding common shares in each class and series on a fully-diluted basis, at all times until and including the later of such time that LICENSEE has received more than [*****] in cash proceeds after the Effective Date of this Agreement from equity investments by parties unaffiliated with LICENSEE as of the Effective Date of this Agreement ("Qualified Investment"). For the avoidance of doubt, such anti-dilution protection for the foregoing shares shall continue to apply through the duration of, and until immediately after, the Qualitied Investment pursuant to this Agreement and any Amendments thereto, whichever is later. Furthermore, LICENSEE shall issue to LICENSOR fully-dilutable common shares equal to [*****] of the total number of LICENSEE common shares in each class and series issued and outstanding. LICENSEE shall affect the issuance of the foregoing fully-diluted shares by concurrent execution of an appropriate Stockholders Agreement, Investor Rights Agreements, and Common Stock Subscription Agreement, together with appropriate Amendments thereto evidencing the foregoing issuance of such fully-dilutable common shares to LICENSOR, the terms of which are incorporated by reference herein.

3. LICENSEE shall pay LICENSOR, as additional consideration for the payment Extension Date granted by LICENSOR under this Amendment. the sum of [*****] dollars, to be due and payable on or before such Extension Date.

4. LICENSOR hereby reserves the right, at its sole and absolute discretion, to impose additional penalties at law or in equity, for the nonpayment by the LICENSEE of any and all license issue fees together with patent fees and costs due and payable by the Extension Date.

5. LICENSOR and LICENSEE mutually agree and confirm that the following sections of the License Agreement remain in full force and effect, and agree to be bound by the terms and conditions specified therein: section 6. entitled INDEMNIFICATION, section 21. entitled AMENDMENT, and section 25. entitled ENTIRE AGREEMENT. LICENSOR and LICENSEE further mutually agree and confirm that in all other respects the License Agreement shall remain in full force and effect in accordance with all other terms and conditions specified therein, and agree to be bound by the terms and conditions set forth therein.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS EXHIBIT MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

This Amendment is entered into and made effective as of the last signature date set forth below.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date set forth below.

LICENSOR:

UNIVERSITY OF MIAMI

By: /s/ Bart Chernow Date: April 20, 2009
Bart Chernow. M.D.
Director of UM Innovation
Vice Provost of Technology Advancement

LICENSEE:

HEAT BIOLOGICS. INC.

By: /s/ Jeffrey Wolf Date: April 20, 2009
Jeffrey Wolf
President

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS EXHIBIT MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

SECOND AMENDMENT TO LICENSE AGREEMENT (UMC-131, UME-139)

Second Amendment to the License Agreement ("Amendment 2") dated the 11 th day of July. 2008 (the "Effective Date"), together with that certain Amendment thereto dated April 29, 2009 ("Amendment 1"), by and between the University of Miami and its School of Medicine ("LICENSOR"), and HEAT BIOLOGICS II, INC., a Delaware corporation ("LICENSEE"), under the direction of Dr. Eckhard Podack, to wit: LICENSE AGREEMENT relating to the technology and product identified as the Podack Antibody Technology (**UMC-131, UME-139**) and hereinafter referred to as "License Agreement".

WHEREAS, LICENSEE has past due and outstanding license issue fee obligations to LICENSOR, as set forth in sections 5.3 and 8.1(a) of the License Agreement in the total amount of [*****] dollars, which were due and payable as follows:

a) [*****] dollars obligation past due and outstanding, to wit: Payable within thirty (30) days of the Effective Date, on or before August 11, 2008.

b) [*****] dollars past due and outstanding, to wit: Payable within one (1) year of the Effective Date; and

WHEREAS, LICENSEE has past due and outstanding patent fees and costs obligations to I,lCENSOR in the amount of [*****] dollars pursuant to section 5.1 of the License Agreement; and

WHEREAS, LICENSEE has a past due and outstanding consideration payment to LICENSOR in the amount of [*****] dollars, for the payment extension granted by LICENSOR in Amendment 1; and

WHEREAS, LICENSEE has past due and outstanding license issue fee obligations together with past due and outstanding patent fees and costs obligations to LICENSOR pursuant to the License Agreement, and a past due and outstanding consideration payment to LICENSOR pursuant to Amendment 1, in the total amount of [*****] dollars; and

WHEREAS, LICENSEE has requested an extension of the payment dates for past due license issue fees, past due patent fees and costs, together with the past due consideration payment, and LICENSOR desires to extend the foregoing payment dates.

NOW THEREFORE, for the mutual promises and other good and valuable consideration contained herein, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

LICENSOR agrees to extend the payment dates of the foregoing past due license issue fees together with past due patent fees and costs owed by LICENSEE pursuant to the License Agreement, together with the past due consideration owed by LICENSEE pursuant to Amendment 1, under the following terms and conditions:

1. LICENSOR shall extend the payment deadline of all past due license issue fees and past due patent fees and costs under the License Agreement, in the total amount of [*****] dollars to February 11, 2010 (the "Extension Date").

2. LICENSEE shall pay LICENSOR as additional consideration for the payment Extension Date granted by LICENSOR under this Agreement 2, the sum of [*****] dollars to be due and payable upon the execution of this Amendment 2. Furthermore, LICENSEE shall pay LICENSOR the past

due and outstanding consideration payment to LICENSOR in the amount of [*****] dollars, for the payment extension granted by LICENSOR in Amendment 1, on or before September 11, 2009. LICENSOR and LICENSEE further mutually agree that in the event LICENSEE does not meet the foregoing past due payment obligation, LICENSOR shall have the option in LICENSOR's sole and absolute discretion, to declare this Amendment 2 null and void.

3. LICENSOR hereby reserves the right, at its sole and absolute discretion, to impose additional penalties at law or in equity, for the nonpayment by the LICENSEE of any and all license issue fees, patent fees and costs, together with past due consideration payments due and payable by the Extension Date.

4. LICENSOR and LICENSEE mutually agree and confirm that the following sections of the License Agreement remain in full force and effect, and agree to be bound by the terms and conditions specified therein: section 6. entitled INDEMNIFICATION, section 21. entitled AMENDMENT, and section 25. entitled ENTIRE AGREEMENT. LICENSOR and LICENSEE further mutually agree and confirm that in all other respects the License Agreement shall remain in full force and effect in accordance with all other terms and conditions specified therein, and agree to be bound by the terms and conditions set forth therein.

5. LICENSOR and LICENSEE mutually agree and confirm that paragraphs 3. and 4. shall survive any nullification of this Amendment 2 by LICENSOR.

This Amendment 2 is entered into and made effective as of the last signature date set forth below.

IN WITNESS WHEREOF, the parties have executed this Amendment 2, as of the date set forth below.

LICENSOR:

UNIVERSITY OF MIAMI
By: /s/ Bart Chernow, M.D.
Bart Chernow, M.D.
Vice Provost of Technology Advancement

Date: August 11, 2009

LICENSEE:

HEAT BIOLOGICS II, INC.
By: /s/ Jeffrey Wolf
Jeffrey Wolf
President

Date: August 11, 2009

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS EXHIBIT MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

LICENSE AGREEMENT

This License Agreement (the "Agreement") is entered into and made effective the 19th day of November, 2013 (the "Effective Date") between UNIVERSITY OF MIAMI and its School of Medicine, whose principal place of business is at 1951 NW 7th Avenue, Suite 110, Miami, Florida 33136 (hereinafter referred to as "MIAMI") and **Pelican Therapeutics, Inc.**, a Delaware corporation, whose principal place of business is at 100 Europa Drive, Suite 420, Chapel Hill, NC 27517 (hereinafter referred to as "COMPANY").

WITNESSETH

WHEREAS, MIAMI is the sole owner of the technology and product identified as the Stimulation of TNFRSF25 with TL1A-Ig Fusion Proteins Technology (UMM-143 and UMN-106);

WHEREAS, MIAMI is the sole owner of the patent rights relating to the Stimulation of TNFRSF25 with TL1A-Ig Fusion Proteins Technology (**UMM-143** and **UMN-106**);

WHEREAS, COMPANY has obtained from MIAMI the patent rights to Treg Expansion (UMI-176) which is related to UMM-143 and UMN-106;

WHEREAS, MIAMI wishes to exclusively license to COMPANY the Stimulation of TNFRSF25 with TL1A-Ig Fusion Proteins Technology (UMM-143 and UMN-106 and patent rights related thereto; and

WHEREAS, COMPANY desires to acquire an exclusive license from MIAMI to the Stimulation of TNFRSF25 with TL1A-Ig Fusion Proteins Technology (UMM-143 and UMN-106) and patent rights related thereto for the purpose of commercially marketing the Stimulation of TNFRSF25 with TL1A-Ig Fusion Proteins Technology (UMM-143 and UMN-106).

NOW THEREFORE, for these and other valuable considerations, the receipt of which is hereby acknowledged, the parties agree as follows:

1. DEFINITIONS:

1.1 "Affiliate" shall mean any corporation or other business entity controlled by, controlling or under common control with COMPANY. For this purpose, "control" shall mean direct or indirect beneficial ownership of at least a fifty percent (50%) of the voting stock of, or at least a fifty percent (50%) interest in the income of such corporation or other business entity, or such other relationship as in fact, constitutes actual control.

1.2 "Sublicensee" as used in this Agreement shall mean any third party to whom COMPANY has granted a license to make, have made, use and/or sell the Product under the Patent Rights, provided said third party has agreed in writing with COMPANY to accept the conditions and restrictions agreed to by COMPANY in this Agreement.

1.3 "Patent Rights" shall mean the following United States Patent applications: **UMM-143**: US Provisional Patent Applications serial number 61/750,672 titled "CLONING, EXPRESSION, AND FUNCTIONAL CHARACTERIZATION OF TL1A-Ig" and filed on January 9, 2013; US Provisional Patent Applications serial number 61/753,634 titled "CLONING, EXPRESSION, AND FUNCTIONAL CHARACTERIZATION OF TL1A-Ig" and filed on January 17, 2013; **UMN-106**: US Provisional Patent Application serial number 61/842,127 titled "Cloning, Expression and Functional Characterization of TL1A-Ig" and all United States patents and foreign patents and patent applications claiming the priority date of the US Provisional Patent Applications; all divisionals, continuations of the foregoing; and those claims in continuations-in-part of the foregoing that are described in sufficient detail in US Provisional Patent Application serial numbers 61/750,672 and/or US Provisional Patent Applications serial number 61/753,634 and/or US Provisional Patent Application serial number 61/842,127 to meet the requirements of 35 U.S.C. 112¶1; and any re-examinations or reissues of the foregoing.

1.4 "Licensed Product" shall mean any product or part thereof which:

(a) is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights; or

(b) is manufactured by using a process which is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights.

1.5 "Licensed Process" shall mean any process practiced in a country in which said process is covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or pending claim contained in the Patent Rights.

1.6 "Net Sales" shall mean the sum of all amounts invoiced on account of sale or use of Licensed Products and Licensed Processes by COMPANY and its Affiliates or any Sublicensees to non-affiliated third party purchasers or users of Licensed Products or Licensed Processes, less (a) discounts to purchasers in amounts customary in the trade, (b) amounts for transportation or shipping charges to purchasers, (c) credits for returns, allowances or trades, and (d) taxes and duties levied on the sale or use of Licensed Products, whether absorbed by COMPANY or paid by the purchaser.

1.7 "Territory" shall mean **worldwide**.

1.8 "Field of Use" shall mean **all human healthcare and research applications**.

1.9 "Licensed Materials" shall mean MIAMI's biological materials in the possession of Dr. Eckhard Podack's laboratory at the Effective Date that are covered in whole or in part by an issued, unexpired, and not adjudicated unenforceable claim or a pending claim contained in the Patent Rights.

1.10 "COMPANY Materials" shall mean any biological materials (e.g., humanized monoclonal antibodies) that COMPANY makes or has made using Licensed Materials or sequence information from any polynucleotides or polypeptides contained in the Licensed Materials.

2. GRANT:

2.1 MIAMI hereby grants to COMPANY an exclusive license, subject to any rights of the U.S. government specified in section 4 below, in the Territory for the Field of Use, with the right to sublicense, under the Patent Rights, to make, have made for its own use and sale, use and sell Licensed Products and Licensed Processes.

2.2 MIAMI also hereby grants to COMPANY an exclusive license to make, use, and/or sell the Licensed Materials in the Territory for the Field of Use. At COMPANY's request, MIAMI shall provide COMPANY with a reasonable amount of Licensed Materials so

that COMPANY may reproduce such Licensed Materials for the purpose of making, selling, or using Licensed Products or Licensed Processes.

2.3 MIAMI reserves to itself the non-transferable right to make and use Licensed Materials, Licensed Products and/or Licensed Processes solely for its internal, non-commercial, scientific research, not-for-profit clinical research, and educational purposes. Except to the extent required by law, MIAMI shall not transfer the Licensed Materials to any third party without first obtaining, in a Material Transfer Agreement, the written agreement of that third party to not use or further distribute such materials for commercial purposes. MIAMI shall notify COMPANY in writing of any third party request for such materials and provide COMPANY at least ten (10) days to object to such request on the basis that such transfer would interfere with the objectives of this Agreement.

2.4 COMPANY hereby grants to MIAMI the non-transferable right to make and use COMPANY Materials solely for its internal, non-commercial scientific research, not-for-profit clinical research, and educational purposes. At MIAMI's request, COMPANY shall provide MIAMI with a reasonable amount of COMPANY Materials solely for the aforesaid purpose. Without the express written consent of COMPANY, MIAMI shall not transfer to a third party any COMPANY Materials or derivatives thereof or any non-public sequence information from any polynucleotides or polypeptides contained in the foregoing.

3. TERM:

The license granted by this Agreement shall be exclusive in the licensed Field of Use for a term commencing as of the effective date of this Agreement and continue until the expiration, on a country by country basis, of all of the Patent Rights.

4. UNITED STATES LAWS:

4.1 COMPANY understands that the Licensed Subject Matter may have been developed under a funding agreement with the Government of the United States of America and, if so, that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to the Government's rights under any agreement and any applicable law or regulation. If there is a conflict between an agreement, applicable law or regulation and this Agreement, the terms of the Government agreement, applicable law or regulation shall prevail.

Specifically, This Agreement is subject to all of the terms and conditions of Title 35 United States Code sections 200 through 204, including an obligation that Licensed Product(s) sold or produced in the United States be "manufactured substantially in the United States," and COMPANY agrees to take all reasonable action necessary on its part as COMPANY to enable MIAMI to satisfy its obligation thereunder, relating to Invention(s).

4.2 It is understood that MIAMI is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the Export Administration Act of 1979), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by COMPANY that COMPANY shall not export data or commodities to certain foreign countries without prior approval of such agency. MIAMI neither represents that a license shall not be required nor that, if required, it shall be issued.

5. PATENT PROTECTION AND INFRINGEMENT:

5.1 COMPANY, during the term of this Agreement, is responsible for the filing and the prosecution and paying of all patents and applications. COMPANY shall keep MIAMI fully apprised on the status of all Patent Rights and shall provide MIAMI the opportunity to make comments and suggestions on all decisions relating to the prosecution of the Patent Rights (e.g., office actions). COMPANY shall in good faith consider incorporating such comments and suggestions unless such incorporation would be contrary to the purposes of this Agreement. Where there is disagreement, MIAMI's comments and opinion shall prevail.

5.2 COMPANY shall promptly notify MIAMI in writing of any claim of Patent Rights infringement which may be asserted against COMPANY or MIAMI, its Affiliates and any sublicensees because of the manufacture, use, promotion and sale of Products.

5.3 COMPANY shall reimburse MIAMI for all past patent fees ([*****] as of October 23, 2013) within thirty (30) days of the Effective Date, relating to the preparation, filing, prosecution, issuance, and maintenance of the Licensed Patents incurred prior to the Effective Date.

5.4 COMPANY will defend, indemnify and hold harmless MIAMI, its Trustees, officers, directors, employees and its Affiliates against any and all judgments and damages arising from any and all third party claims of Patent Rights infringement which may be asserted against MIAMI, and Affiliates because of the manufacture, use, promotion and sale of Licensed Products. COMPANY will bear all costs and expenses incurred in connection with the defense of any such claims or as a result of any settlement made or judgment rendered on the basis of such claims. MIAMI shall have no further liability to COMPANY for any loss or damages COMPANY may incur as a result of the invalidity of MIAMI'S Patent Rights. MIAMI will have the right, but not the obligation to retain counsel at its expense in connection with any such claim. MIAMI at its option, shall have the right, within thirty days after commencement of such action, to intervene and take over the sole defense of the action at its own expense.

5.5 Upon learning of any infringement of Patent Rights by third parties in any country, COMPANY and MIAMI will promptly inform each other, as the case may be, in writing of that fact and will supply the other with any available evidence pertaining to the infringement. COMPANY at its own expense, shall have the option to take whatever steps are necessary to stop the infringement at its expense and recover damages therefore. If requested by COMPANY, MIAMI will join in any legal actions enforcing or defending the Patent Rights against third parties deemed necessary or advisable by COMPANY to prevent or seek damages, or both, from the infringement of the Patent Rights provided that COMPANY funds all costs associated with such actions, using counsel mutually acceptable to COMPANY and MIAMI, and indemnifies and holds MIAMI harmless with respect to any claims or damages made against or sustained by MIAMI in connection with such involvement. In the event that MIAMI and COMPANY mutually bring suit, costs and expenses shall be borne by COMPANY, and any recovery shall be shared by the parties as if such infringing sales were Net Sales. In any event, no settlement, consent, judgment or other voluntary final disposition of the suit may be entered into without the consent of MIAMI, which shall not be unreasonably withheld. In the event COMPANY does not take steps to stop the infringement, MIAMI shall have the right to bring suit at its own expense. In such event, financial recoveries will be entirely retained by MIAMI.

5.6 MIAMI shall have no responsibility with respect to COMPANY's own trademarks and tradename, and COMPANY in respect to the use thereof will defend, indemnify and hold harmless MIAMI against any and all third party claims.

6. INDEMNIFICATION:

6.1 COMPANY agrees to release, indemnify and hold harmless the MIAMI, its trustees, officers, faculty, employees, Affiliates, agents and students against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including reasonable attorney's fees through the appellate levels) which may be brought against MIAMI, its trustees, officers, faculty, employees, Affiliates, agents and/or students as a result of or arising out of any willful misconduct or negligent act or omission of COMPANY, its agents, or employees, or arising out of use, production, manufacture, sale, lease, consumption or advertisement by COMPANY or any third party, including any Sublicensees of any Licensed Product, Licensed Patent, Licensed Process, or Licensed Materials covered by this Agreement.

6.2 MIAMI agrees to release and hold harmless the COMPANY, its directors, officers, employees, Affiliates, Sublicensees, and agents against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including reasonable attorney's fees through the appellate levels) which may be brought against COMPANY, its directors, officers, employees, Affiliates, Sublicensees, and/or agents as a result of or arising out of any willful misconduct, or negligent act or omission of MIAMI; or, except where caused by COMPANY's negligence or willful misconduct, arising out of use, sale, lease, consumption or advertisement by MIAMI of any COMPANY Materials covered by this Agreement.

6.3 This Agreement to reimburse and indemnify under the circumstances set forth above shall continue after the termination of this Agreement.

7. NO REPRESENTATIONS/WARRANTIES:

7.1 MIAMI hereby represents and warrants to COMPANY that MIAMI owns the Patent Rights and Licensed Materials and has not assigned any rights therein or given any license or other rights thereto to any party other than COMPANY.

7.2 MIAMI hereby represents and warrants that, although it has not conducted any investigation, it has no knowledge of any patents or patent applications, other than the Patents Rights, that contain a claim that would be infringed by the sale or use of a Licensed Product, Licensed Process, or Licensed Materials.

7.3 EXCEPT AS PROVIDED ABOVE, MIAMI MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AND HEREBY DISCLAIMS ALL SUCH WARRANTIES, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE CONDITION OF ANY INVENTION(S) OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, LICENSED UNDER THIS AGREEMENT; OR THE MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE INVENTION OR PRODUCT; OR THAT THE USE OF THE LICENSED PRODUCT WILL NOT INFRINGE ANY PATENT, COPYRIGHTS, TRADEMARKS, OR OTHER RIGHTS. MIAMI SHALL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY ANY COMPANY OR ANY THIRD PARTIES RESULTING FROM THE USE, PRODUCTION, MANUFACTURE, SALE, LEASE, CONSUMPTION, OR ADVERTISEMENT OF THE PRODUCT.

7.4 The provisions of this Section shall continue beyond the termination of this Agreement.

8. ROYALTIES:

8.1 In consideration of the license herein granted, COMPANY shall pay royalties to MIAMI as follows:

(a) COMPANY agrees to pay to MIAMI a license issue fee of $35,000, of which [*****] is due within 30 days of signing this Agreement. Further, COMPANY agrees to pay MIAMI the remaining license issue fee of [*****] in the following manner: [*****] by December 1, 2013 and [*****] by April 1, 2014.

(b) In the event that COMPANY terminates its license to UMI-176 (see the recitals), COMPANY agrees to pay MIAMI minimum royalty payments, as follows:

Payment	Year
[$10,000]	2014
[$20,000]	2015 and every year thereafter on the same date, for the life of this Agreement.

The minimum royalty shall be paid for each year after the UMI-176 license has been terminated. No minimum royalty shall be due under this Agreement for any year in which the UMI-176 license is in force. The minimum royalty payment shall be due on or before May 31 of the calendar year. Any minimum royalty paid in a calendar year will be credited against the earned royalties for that calendar year. It is understood that the minimum royalties will be applied to earned royalties on a calendar year basis, and that sales of Licensed Products and/or Licensed Processes requiring the payment of earned royalties made during a prior or subsequent calendar year shall have no effect on the annual minimum royalty due MIAMI for other than the same calendar year in which the royalties were earned.

(c) COMPANY agrees to pay to MIAMI as earned royalties a royalty calculated as a percentage of COMPANY's Net Sales of Licensed Products which, if not for this Agreement, would infringe the Patent Rights, in accordance with the terms and conditions of this Agreement. The royalty is deemed earned as of the earlier of the date the Licensed Product and/or Licensed Process is actually sold and paid for, the date an invoice is sent by COMPANY, or the date a Licensed Product and/or Licensed Process is transferred to a third party for any promotional reasons. The royalty shall remain fixed while this Agreement is in effect at a rate of [*****] of Net Sales.

(d) For a sublicense, COMPANY shall pay to MIAMI an amount equal to [*****] of what COMPANY would have been required to pay to MIAMI had COMPANY sold the amount of Licensed Products sold by the Sublicensees. In addition, if COMPANY receives any fees, minimum royalties, or other payments in consideration for any rights granted under a Sublicense, and such payments are not based directly upon the amount or

value of Licensed Products or Licensed Processes sold by the Sublicensees nor represent payment of costs to COMPANY for a development program which COMPANY is obligated to perform under such sublicense, then COMPANY shall pay MIAMI [*****] of such payments.

(e) In addition to all other payments required under this Agreement, in the event that COMPANY terminates its license to UMI-176, COMPANY agrees to pay MIAMI milestone payments, as follows:

Payment	Event
[$25,000]	Upon submission of an IND for a Licensed Product
[$25,000]	Upon approval of an IND for a Licensed Product
[$100,000]	Upon completion of a phase 1 clinical trial for a Licensed Product
[$250,000]	By the earlier of May 31, 2022 or the approval of an NDA for a Licensed Product

(f) In the event that licenses from third parties are required by COMPANY in order to make, have made, use, sell, offer to sell or import any particular Licensed Product or Licensed Process, then the earned royalty which COMPANY is obligated to pay MIAMI under this Agreement shall be reduced by [*****] for each one dollar ($1.00) in royalties which COMPANY is obligated to pay to third parties under such licenses, further provided, however, that the royalties payable to MIAMI under this Section shall not be reduced to less than [*****]of the applicable Net Sales.

(g) In the event that COMPANY requires more than one license from the MIAMI to make, have made for its use, sell, offer to sell or import any

particular Licensed Product or Licensed Process as defined in sections 1.4 and 1.5, respectively, of this Agreement, then the combined earned royalties shall not exceed [*****] of Net Sales and any sublicense fees shall not exceed [*****] of what COMPANY would have been required to pay to MIAMI had COMPANY sold the amount of Licensed Products sold by the Sublicensees.

8.2 All payments shall be made hereunder in U.S. dollars; provided however, that if the proceeds of the sales upon which such royalty payments are based are received by the COMPANY in a foreign currency or other form that is not convertible or exportable in dollars, and the COMPANY does not have ongoing business operations or bank accounts in the country in which the currency is not convertible or exportable, the COMPANY shall pay such royalties in the currency of the country in which such sales were made by depositing such royalties in MIAMI'S name in a bank designated by MIAMI in such country. Royalties in dollars shall be computed by converting the royalty in the currency of the country in which the sales were made at the exchange rate for dollars prevailing at the close of the business day of the COMPANY'S quarter for which royalties are being calculated as published the following day in the Wall Street Journal (or, if it ceases to be published, a comparable publication to be agreed upon from time to time by the parties), and with respect to those countries for which rates are not published in the Wall Street Journal, the exchange rate fixed for such date by the appropriate United States governmental agency.

8.3 In the event the royalties set forth herein are higher than the maximum royalties permitted by the law or regulations of a particular country, the royalty payable for sales in such country shall be equal to the maximum permitted royalty under such law or regulation.

8.4 In the event that any taxes, withholding or otherwise, are levied by any taxing authority in connection with accrual or payment of any royalties payable to MIAMI under this Agreement, the COMPANY shall have the right to pay such taxes to the local tax authorities on behalf of MIAMI and the payment to MIAMI of the net amount due after reduction by the amount of such taxes, shall fully satisfy the COMPANY'S royalty obligations under this Agreement.

9. DILIGENCE:

9.1 COMPANY shall use efforts at least sufficient to meet the requirements of the Bayh-Dole Act to manufacture, market and sell the Licensed Products in the Territory, and to create a demand for the Products.

9.2 COMPANY agrees to submit reports, upon MIAMI's request but no more than every 6 months as to its efforts to develop markets for the Licensed Products. Such reports shall include assurance by COMPANY of its intent to actively develop commercial embodiments of Licensed Products and a summary of its efforts in this regard.

9.3 Unless COMPANY has introduced a Licensed Product into the commercial marketplace in one of the three major markets (European Union, Japan and the United States) or has made best efforts (for avoidance of doubt it will be presumed that COMPANY has used best efforts if it has a Licensed Product in a phase III clinical trial) to achieve the same prior to December 31, 2022 COMPANY agrees that MIAMI may terminate this Agreement by providing COMPANY ninety (90) advanced written notice of its intent to terminate this Agreement. In the event the payment of earned royalties, once begun and if any are due, ceases for more than two (2) calendar quarters, and COMPANY fails to cure this breach within two (2) months after being provided written notice of same, MIAMI may terminate this Agreement.

10. REPORTS AND RECORDS:

10.1 During the term of this Agreement and before the COMPANY launches sale of Licensed Products, COMPANY shall provide semi-annual report due June 30, and December 31 of each calendar year detailing COMPANY's research and development activities and efforts. Further, after commencing the first sale, the COMPANY shall furnish to MIAMI reports on a quarterly specifying during the preceding calendar quarter (a) the number or amount of Licensed Products sold hereunder by COMPANY, and/or its Affiliates or Sublicensees, (b) the total billings for all Licensed Products sold, (c) deductions as applicable in paragraph 1.6, (d) total royalties due, (e) names and addresses of all Sublicensees. Such reports shall be due within forty-five (45) days following the last day of each calendar quarter in each year during the term of this Agreement. Each such report shall be accompanied by payment in full of the amount due MIAMI in United States dollars calculated in accordance with Section 8.1 hereof.

10.2 For a period of three (3) years from the date of each report pursuant to Paragraph 10.1, COMPANY, shall keep records adequate to verify each such report and accompanying payment made to MIAMI under this Agreement, and an independent certified public accountant or accounting firm selected by MIAMI and acceptable to COMPANY may have access, on reasonable notice during regular business hours, not to exceed once per year, to such records to verify such reports and payments. Such accountant or accounting firm shall not disclose to MIAMI any information other than that information relating solely to the accuracy of, or necessity for, the reports and payments made hereunder. The fees and expense of the certified public accountant or accounting firm performing such verification shall be borne by MIAMI unless in the event that the audit reveals an underpayment of royalty by more than [*****], the cost of the audit shall be paid by COMPANY.

11. MARKING AND STANDARDS:

11.1 Prior to the issuance of patents on the Invention(s), COMPANY agrees to mark and have sublicensees mark Licensed Products (or their containers or labels) made, sold, or otherwise disposed of by it under the license granted in this Agreement with a proper patent notice as specified under the patent laws of the United States.

11.2 COMPANY further agrees to maintain satisfactory standards in respect to the nature of the Licensed Products manufactured and/or sold by COMPANY. COMPANY, agrees that all Licensed Products manufactured and/or sold by it shall be of a quality which is appropriate to products of the type here involved. COMPANY agrees that similar provisions shall be included in sublicenses of all tiers.

12. ASSIGNMENT:

12.1 This Agreement is not assignable by COMPANY or by operation of law without the prior written consent of MIAMI at its sole discretion except that COMPANY shall have the right to transfer or assign this Agreement to any entity which acquires all or substantially all of COMPANY's assets provided that COMPANY gives MIAMI thirty (30) days advance written notice of the intended assignment and considers in good faith any of MIAMI's concerns relating to the intended assignment. The foregoing sentence shall not be construed to require COMPANY to obtain MIAMI's approval of any Sublicensees.

12.2 This Agreement shall extend to and be binding upon the successors and legal representatives and permitted assigns of MIAMI and COMPANY.

13. NOTICE:

Any notice, payment, report or other correspondence (hereinafter collectively referred to as "correspondence") required or permitted to be given hereunder shall be mailed by certified mail or delivered by hand to the party to whom such correspondence is required or permitted to be given hereunder. If mailed, any such notice shall be deemed to have been given when mailed as evidenced by the postmark at point of mailing. If delivered by hand, any such correspondence shall be deemed to have been given when received by the party to whom such correspondence is given, as evidenced by written and dated receipt of the receiving party.

All correspondence to COMPANY shall be addressed as follows:

CEO
Pelican Therapeutics, Inc.
100 Europa Drive, Suite 420
Chapel Hill, NC 27517

All correspondence to MIAMI shall be addressed, in duplicate, as follows:

FOR NOTICE:

Vice President
Business Affairs
327 Max Orovitz Building
1507 Levante Avenue
Coral Gables, Florida 33124-1432

FOR NOTICE AND PAYMENT:

Office of Technology Transfer
University of Miami

1951 NW 7th Avenue, Suite 110

Miami, FL 33136

Either party may change the address to which correspondence to it is to be addressed by notification as provided herein.

14. TERMINATION:

14.1 A party shall have the right to terminate this Agreement if the other party commits (a) a material breach of an obligation under this Agreement or (b) provides a false report, and continues in breach for more than ninety (90) days after receiving unambiguous written notice of such breach or false report; however, in the event COMPANY breaches its obligations under Sections five (5) or eight (8) above, COMPANY shall have thirty (30) days after receiving written notice to cure such breach, after which MIAMI shall have the right to terminate this Agreement. Such termination shall be effective upon further written notice to the breaching party after failure by the breaching party to cure such default.

14.2 The license and rights granted in this Agreement have been granted on the basis of the special capability of COMPANY to perform research and development work leading to the manufacture and marketing of the Products. Accordingly, COMPANY covenants and agrees that in the event any proceedings under the Bankruptcy Act or any amendment thereto, be commenced by or against COMPANY, and, if against COMPANY, said proceedings shall not be dismissed with prejudice before either an adjudication in bankruptcy or the confirmation of a composition, arrangement, or plan of reorganization, or in the event COMPANY shall be adjudged insolvent or make an assignment for the benefit of its creditors, or if a writ of attachment or execution be levied upon the license hereby created and not be released or satisfied within ten (10) days thereafter, or if a receiver be appointed in any proceeding or action to which COMPANY is a party with authority to exercise any of the rights or privileges granted hereunder and such receiver be so discharged within a period of forty-five (45) days after his appointment, any such event shall be deemed to constitute a breach of this Agreement by COMPANY and, MIAMI, at the election of MIAMI, but not otherwise, ipso facto, and without notice or other action by MIAMI, shall terminate this Agreement and all rights of COMPANY hereunder and all rights of any and all persons claiming under COMPANY.

14.3 COMPANY shall have the right to terminate this Agreement by providing ninety (90) days written notice of its intent to terminate this Agreement to MIAMI.

14.4 Any termination of this Agreement shall be without prejudice to MIAMI's right to recover all amounts accruing to MIAMI prior to such termination and cancellation. Except as otherwise provided, should this Agreement be terminated for any reason, COMPANY shall have no rights, express or implied, under any patent property which is the subject matter of this Agreement, nor have the right to recover any royalties paid MIAMI hereunder. Upon termination, COMPANY shall have the right to dispose of Licensed Products then in their possession and to complete existing contracts for such products, so long as contracts are completed within six (6) months from the date of termination, subject to the payment of royalties to MIAMI as provided in Section 8 hereof.

15. CERTIFICATE OF INSURANCE:

15.1 At least thirty (30) days before it causes a Licensed Product to be administered to a human subject, COMPANY shall obtain (and thereafter shall maintain) and provide proof of liability insurance coverage for the Product in the amount of three million dollars ($3,000,000) and at no expense to MIAMI, COMPANY shall name MIAMI as an additional insured. Within fourteen (14) days before it causes a Licensed Product to be administered to a human subject, COMPANY shall provide a certificate of such product liability insurance to MIAMI. COMPANY agrees to carry and keep in force, at its expense, general liability insurance with limits not less than $1,000,000 per person and $3,000,000 aggregate to cover liability for damages on account of bodily or personal injury or death to any person, or damage to property of any person. Such insurance shall contain an endorsement naming the University of Miami as an additional insured with respect to this Agreement. Within fourteen (14) days of the Effective Date, COMPANY shall provide a certificate of such general liability insurance to MIAMI. Insurance Certificates should be sent to the University of Miami upon execution of this Agreement and on the anniversary of that date every year thereafter, Office of Technology Transfer, 1951 NW 7th Avenue, Suite 110, Miami, Florida 33136.

15.2 COMPANY shall not cancel such insurance without thirty (30) days prior notice to MIAMI. Such cancellation shall be cause for termination.

15.3 The terms of this provision shall extend beyond termination of the agreement.

16. USE OF NAME:

COMPANY shall not use the name of the University of Miami, or any of its employees, or any adaptation thereof, in any publication, including advertising, promotional or sales literature without the prior written consent of Mr. Humberto Speziani, Vice President of Business Services, 327 Max Orovitz Bldg., 1507 Levante Avenue, Coral Gables, FL 33124-1432. MIAMI shall notify COMPANY within ten (10) days of being provided notice of its decision regarding each instance of intended use of name(s) name(s). The absence of a response by MIAMI within this ten (10) day period shall constitute implied permission for COMPANY to use such name in that instance. Any press releases concerning this Agreement must be mutually agreed upon by the parties.

17. GOVERNING LAW:

This Agreement shall be governed by and interpreted in accordance with the laws of the State of Florida.

18. CAPTIONS:

The captions and paragraph heading of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

19. SEVERABILITY:

Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provision shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such part or provision in valid and enforceable manner, and the remainder of the Agreement shall remain binding upon the parties hereto.

20. SURVIVAL:

20.1 The provisions of Sections 5, 6 and 7 shall survive the termination or expiration of this Agreement and shall remain in full force and effect.

20.2 The provisions of this Agreement which do not survive termination or expiration hereof (as the case may be) shall, nonetheless, be controlling on, and shall be used in construing and interpreting, the rights and obligations of the parties hereto with regard to any dispute, controversy or claim which may arise under, out of, in connection with, or relating to this Agreement.

21. AMENDMENT:

No amendment or modification of the terms of this Agreement shall be binding on either party unless reduced to writing and signed by an authorized officer of the party to be bound.

22. WAIVER:

No failure or delay on the part of a party in exercising any right hereunder will operate as a waiver of, or impair, any such right. No single or partial exercise of any such right will preclude any other or further exercise thereof or the exercise of any other right. No waiver of any such right will be deemed a waiver of any other right hereunder.

23. CONFIDENTIALITY:

Each Party shall maintain all information of the other Party which is treated by such other Party as proprietary or confidential (referred to herein as "Confidential Information") in confidence, and shall not disclose, divulge or otherwise communicate such confidential information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and each party hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such confidential information by any of its Affiliates, directors, officers, employees, consultants, subcontractors, subCOMPANYs or agents. COMPANY's Confidential Information includes but is not limited to the development plan, development reports and all other financial and business reports, strategies, and agreements (including sublicenses) of COMPANY. The parties agree to keep the terms of this Agreement confidential, provided that each party may disclose this Agreement to

their authorized agents and investors who are bound by similar confidentiality provisions. Notwithstanding the foregoing, Confidential Information of a party shall not include information which: (a) was lawfully known by the receiving party prior to disclosure of such information by the disclosing party to the receiving party; (b) was or becomes generally available in the public domain, without the fault of the receiving party; (c) is subsequently disclosed to the receiving party by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed, provided that the receiving party making such disclosure shall take all reasonable steps to restrict and maintain to the extent possible confidentiality of such disclosure and shall provide reasonable notice to the other party to allow such party the opportunity to oppose the required disclosure; or (e) has been independently developed by employees or others on behalf of the receiving party without access to or use of disclosing party's information as demonstrated by written record. Each party's obligations under this Section shall extend for a period of five (5) years from termination or expiration of this Agreement.

24. UNIVERSITY RULES AND REGULATIONS:

COMPANY understands and agrees that University of Miami personnel who are engaged by COMPANY, whether as consultants, employees or otherwise, or who possess a material financial interest in COMPANY, are subject to the University of Miami's rule regarding outside activities and financial interests, and the University of Miami's Intellectual Property Policy. Any term or condition of an agreement between COMPANY and such University of Miami personnel which seeks to vary or override such personnel's obligations to the University of Miami may not be enforced against such personnel, or the University of Miami, without the express written consent of an individual authorized to vary or waive such obligations on behalf of the University of Miami.

25. ENTIRE AGREEMENT:

This Agreement constitutes the entire agreement between the parties hereto respecting the subject matter hereof, and supersedes and terminates all prior agreements respecting the subject matter hereof, whether written or oral, and may be amended only by an instrument in writing executed by both parties hereto.

26. CONTRACT FORMATION AND AUTHORITY:

MIAMI and COMPANY each warrant and represent that the persons signing this Agreement on its behalf have authority to execute this Agreement and that the execution of this Agreement does not violate any law, rule or regulation applicable to it or any contract or other agreement by which it is bound.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective officers thereunto duly authorized to be effective as of the Effective Date.

[SIGNATURE PAGE FOLLOWS]

PELICAN THERAPEUTICS, INC.

Date: 11/19/13

By: /s/ Josiah Hornblower
Name Josiah Hornblower
Title President, Pelican Therapeutics, Inc.

UNIVERSITY OF MIAMI

Date: 11/11/13

By: /s/ Norma Sue Kenyon
Name Norma Sue Kenyon
Title Vice Provost for Innovation

Exhibit 10.27

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS EXHIBIT MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

DP160012
Josiah Hornblower

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

STATE OF TEXAS
COUNTY OF TRAVIS

This **CANCER RESEARCH GRANT CONTRACT** ("**Contract**") is by and between the Cancer Prevention and Research Institute of Texas ("**CPRIT**"), hereinafter referred to as the "**INSTITUTE**", acting through its Chief Executive Officer, and **Pelican Therapeutics,** hereinafter referred to as the "**RECIPIENT**", acting through its authorized signing official.

RECITALS

WHEREAS. pursuant to TEX. HEALTH & SAFETY CODE. Ch. 102, the INSTITUTE may make grants to public and private persons in this state for research into the causes and cures for all types of cancer in humans; facilities for use in research into the causes and cures for cancer; research to develop therapies. protocols. medical pharmaceuticals. or procedures for the cure or substantial mitigation of all types of cancer; and cancer prevention and control programs.

WHEREAS. Article III. Section 67 of the Texas Constitution expressly authorizes the State of Texas to sell general obligation bonds on behalf of the INSTITUTE and for the INSTITUTE to use the proceeds from the sale of the bonds for the purposes of cancer research and prevention programs in this state.

WHEREAS. the INSTITUTE issued a request for applications for RFA P-16-NEWCO-1: New Company Product Development Awards on or about August 2015.

WHEREAS. pursuant to TEX. HEALTH & SAFETY CODE § 102.251. and after a review by the INSTITUTE's scientific research and prevention program committees. the INSTITUTE has approved a Grant (defined below) to be awarded to the RECIPIENT.

WHEREAS. to ensure that the Grant provided to the RECIPIENT pursuant to this Contract is utilized in a manner consistent with Tex. Const. Article III. Section 67 and other laws. and in exchange for receiving such Grant. the RECIPIENT agrees to comply with certain conditions and deliver certain performance.

WHEREAS. the RECIPIENT and the INSTITUTE desire to set forth herein the provisions relating to the awarding of such monies and the disbursement thereof to the RECIPIENT.

IN CONSIDERATION of the Grant and the premises. covenants. agreements. and provisions contained in this Contract. the parties agree to the following terms and conditions:

Article I
DEFINITIONS

The following terms shall have the following meaning throughout this Contract and any Attachments and amendments. Other terms may be defined elsewhere in this Contract.

(1) **Collaborator** - any entity other than the RECIPIENT having one or more personnel participating in the Project and (a) designated as a collaborator in the application submitted by the RECIPIENT requesting the Grant funds awarded by the INSTITUTE, or (b) otherwise approved in writing as a collaborator by the INSTITUTE.

(2) **Contractor** - any person or entity, other than a Collaborator or the RECIPIENT (or their respective personnel), who is contracted by the RECIPIENT to perform activities for the Project.

(3) **Equipment** - an article of tangible, nonexpendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit.

(4) **Grant** - the funding assistance authorized by TEX. HEALTH & SAFETY CODE, Ch. 102 in the amount specified in Section 2.01 and awarded by the INSTITUTE to the RECIPIENT to carry out the Project pursuant to the terms and conditions of this Contract.

(5) **Indirect Costs** - the expenses of doing business that are not readily identified with a particular grant, contract, project, function or activity, but are necessary for the general operation of the organization or the performance of the organization's activities.

(6) **Institute-Funded Activity** - all aspects of work conducted on or as part of the Project.

(7) **Non-Profit Organization** - a university or other institution of higher education or an organization of the type described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501 (c)(3)) and exempt from taxation under 501 (a) of the Internal Revenue Code (26 U.S.C. 501 (a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(8) **Principal Investigator/Program Director** - the individual designated by the RECIPIENT to direct the Project who is principally responsible and accountable to the RECIPIENT and the INSTITUTE for the proper conduct of the Project. References herein to "Principal Investigator/Program Director" include Co-Principal Investigators or Co-Program Directors as well. The Principal Investigator/Program Director and Co-Principal Investigators or Co-Program Directors are set forth on Attachment A.

(9) **Project** - the activities specified or generally described in the Scope of Work or otherwise in this Contract (including without limitation any of the Attachments to the Contract) that are

approved by the INSTITUTE for funding, regardless of whether the INSTITUTE funding constitutes all or only a portion of the financial support necessary to carry them out.

(10) **Recipient Personnel** - The RECIPIENT's Principal Investigator/Program Director and RECIPIENT's employees and consultants working on the Project.

Article II
GRANT AWARD

Section 2.01 Award of Monies. In accordance with the provisions of this Contract and any applicable agency administrative rules, the INSTITUTE shall disburse the proceeds of the Grant to the RECIPIENT in an amount not to exceed **$ 15,245,222** to be used solely for the Project. This award is subject to compliance with the Scope of Work and demonstration of progress towards achievement of the milestones set forth in Section 2.02. This Grant is not intended to be a loan of money.

Section 2.02 Scope of Work and Milestones. The RECIPIENT shall perform the Project in accordance with this Agreement and as outlined in Application **DP160012** submitted by the RECIPIENT and approved by the INSTITUTE. The RECIPIENT shall conduct the Project within the State of Texas with Texas-based employees, Contractors and/or Collaborators unless otherwise specified in the Scope of Work or the Approved Budget. The INSTITUTE and the RECIPIENT hereby adopt the terms of Attachment A in their entirety, incorporate them as if fully set forth herein, and agree that the Project description, goals, timeline and milestones included as Attachment A accurately reflect the Scope of Work of the Project to be undertaken by the RECIPIENT (the "**Scope of Work**") and the milestones expected to be achieved. RECIPIENT and the INSTITUTE mutually agree that the outcome of scientific research is unpredictable and cannot be guaranteed. The RECIPIENT shall use commercially reasonable efforts to complete the goals of the Project pursuant to the timeline reflected in Attachment A and shall timely notify the INSTITUTE if circumstances occur that materially and adversely affect completion thereof. Modifications, if any, to the Scope of Work must be agreed to in writing by both parties as set forth in Section 2.06 "Amendments and Modifications" herein. Material changes to the Scope of Work include, but are not limited to, changes in key personnel involved with the Project, the site of the Project, and the milestones expected to be achieved.

Section 2.03 Contract Term. The Contract shall be effective as of **June 01, 2016** (the "**Effective Date**") and terminate on **May 31, 2019** or in accordance with the Contract termination provisions set forth in Article VIII herein, whichever shall occur first (the "**Termination Date**"). Unless otherwise approved by the INSTITUTE as evidenced by written communication from the INSTITUTE to the RECIPIENT and appended to the Contract, Grant funds distributed pursuant to the Contract shall be expended no earlier than the Effective Date or subsequent to the Termination Date. If, as of the Termination Date, the RECIPIENT has not used Grant money awarded by the INSTITUTE for permissible services, expenses, or costs related to the Project and has not received approval from the INSTITUTE for a no cost extension to the contract term pursuant to Section 3.11 "Carry Forward of Unspent Funds and No Cost Extension" herein, then the RECIPIENT shall not be entitled to retain such unused Grant funds from the

INSTITUTE. Certain obligations as set forth in Section 9.09 of this Contract shall extend beyond the Termination Date.

Section 2.04 Contract Documentation. The Contract between the INSTITUTE and the RECIPIENT shall consist of this final, executed Contract, including the following Attachments to the Contract, all of which are hereby incorporated by reference:

(a) Attachment A - Project Description, Goals and Timeline

(b) Attachment B -Approved Budget, including changes approved by the INSTITUTE subsequent to execution of the Contract.

(c) Attachment C - Assurances and Certifications

(d) Attachment D - Intellectual Property and Revenue Sharing

(e) Attachment E - Reporting Requirements

(f) Attachment F -Approved Amendments to Contract, excluding budget amendments reflected in Attachment B.

Section 2.05 Entire Agreement. All agreements, covenants, representations, certifications and understandings between the parties hereto concerning this Contract have been merged into this written Contract. No prior contemporaneous representation, agreement or understanding, express or implied, oral or otherwise, of the parties or their agents that may have related to the subject matter hereof in any way shall be valid or enforceable unless embodied in this Contract.

Section 2.06 Amendments and Modifications. Requested amendments and modifications to the Contract must be submitted in writing to the INSTITUTE for review and approval (such approval shall not be unreasonably withheld.) Amendments and modifications (including alterations, additions, deletions, assignments and extensions) to the terms of this Contract shall be made solely in writing and shall be executed by both parties. The approved amendment shall be reflected in Attachment A if it is change to the Scope of Work, or as part of Attachment B if it is a budget amendment, or as part of Attachment F for all other changes.

Section 2.07 Relationship of the Parties The RECIPIENT shall be responsible for the conduct of the Project that is the subject of this Contract and shall direct the activities and at all times be responsible for the performance of Recipient Personnel, Collaborators, Contractors and other agents. The INSTITUTE does not assume responsibility for the conduct of the Project or any Institute-Funded Activity that is the subject of this Contract. The INSTITUTE and the RECIPIENT shall perform their respective obligations under this Contract as independent contractors and not as agents, employees, partners, joint venturers, or representatives of the other party. Neither party is permitted to make representations or commitments that bind the other party.

Section 2.08 Subcontracting. Any and all subcontracts entered into by the RECIPIENT in relation to the performance of activities under the Project shall be in writing and shall be subject to the requirements of this Contract. Without in any way limiting the foregoing, the RECIPIENT shall enter into and maintain a written agreement with each such permitted Contractor with terms and conditions sufficient to ensure the RECIPIENT fully complies with the terms of this Contract, including without limitation the terms set forth in Attachments C, D, and E. The RECIPIENT agrees that it shall be responsible to the INSTITUTE for the performance of and payment to any Contractor. Any reimbursements made by the RECIPIENT to a Contractor shall be made in accordance with the applicable provisions of TEX. GOV'T. CODE, Ch. 2251.

Section 2.09 Transfer or Assignment by the Recipient. This Contract is not transferable or otherwise assignable by the RECIPIENT, whether by operation of law or otherwise, without the prior written consent of the INSTITUTE, except as provided in this Section 2.09. Any such attempted transfer or assignment without the prior written consent of the INSTITUTE (except as provided in this Section 2.09) shall be null, void and of no effect. For purposes of this section, an assignment or transfer of this Contract by the RECIPIENT in connection with a merger, transfer or sale of all or substantially all of the RECIPIENT's assets or business related to this Contract or a consolidation, change of control or similar transaction involving the RECIPIENT shall not be deemed to constitute a transfer or assignment, so long as such action does not impair or otherwise negatively impact the revenue sharing terms in Attachment D. Nothing herein shall be interpreted as superseding the requirement that the Project be undertaken in Texas with Texas-based employees.

If the Principal Investigator leaves the employment of the RECIPIENT or is replaced by the RECIPIENT for any reason during the course of the Grant with someone who is not already designated a co-Principal Investigator in the Application, the RECIPIENT shall notify the INSTITUTE prior to replacing the Principal Investigator. Written approval by the INSTITUTE is required for the replacement of the Principal Investigator with someone who is not already a co-Principal Investigator in the Application, which approval shall not be unreasonably withheld, conditioned or delayed.

Section 2.10 Representations and Certifications. The RECIPIENT represents and certifies to the best of its knowledge and belief to the INSTITUTE as follows:

(a) It has legal authority to enter into, execute, and deliver this Contract, and all documents referred to herein, and it has taken all actions necessary to its execution and delivery of such documents;

(b) It will comply with all of the terms, conditions, provisions, covenants, requirements, and certifications in this Contract, applicable statutory provisions, agency administrative rules, and all other documents incorporated herein by reference;

(c) It has made no material false statement or misstatement of fact in connection with this Contract and its receipt of the Grant, and all of the information it previously

submitted to the INSTITUTE or that it is required under this Contract to submit to the INSTITUTE relating to the Grant or the disbursement of any of the Grant is and will be true and correct at the time such statement is made;

(d) It is in compliance in all material respects with provisions of its charter and of the laws of the State of Texas, and of the laws of the jurisdiction in which it was formed, and (i) there are no actions, suits, or proceedings pending, or threatened, before any judicial body or governmental authority against or affecting its ability to enter into this Contract, or any document referred to herein, or to perform any of the material acts required of it in such documents and (ii) it is not in default with respect to any order, writ, injunction, decree, or demand of any court or any governmental authority which would impair its ability to enter into this Contract, or any document referred to herein, or to perform any of the material acts required of it in such documents;

(e) Neither the execution and delivery of this Contract or any document referred to herein, nor compliance with any of the terms, conditions, requirements, or provisions contained in this Contract or any documents referred to herein, is prevented by, is a breach of, or will result in a breach of, any term, condition, or provision of any agreement or document to which it is now a party or by which it is bound; and

(f) It shall furnish such satisfactory evidence regarding the representations and certifications described herein as may be required and requested by the INSTITUTE from time to time.

Section 2.11 Reliance upon Representations. By awarding the Grant and executing this Contract, the INSTITUTE is relying, and will continue to rely throughout the term of this Contract, upon the truthfulness, accuracy, and completeness of the RECIPIENT's written assurances, certifications and representations. Moreover, the INSTITUTE would not have entered into this Contract with the RECIPIENT but for such written assurances, certifications and representations. The RECIPIENT acknowledges that the INSTITUTE is relying upon such assurances, certifications and representations and acknowledges their materiality and significance.

Section 2.12 Contingent upon Availability of Grant Funds. This Contract is contingent upon funding being available for the term of the Contract and the RECIPIENT shall have no right of action against the INSTITUTE in the event that the INSTITUTE is unable to perform its obligations under this Contract as a result of the suspension, termination, withdrawal, or failure of funding to the INSTITUTE or lack of sufficient funding of the INSTITUTE for this Contract. If funds become unavailable to the INSTITUTE during the term of the Contract, Section 8.01(c) shall apply. For the sake of clarity, and except as otherwise provided by this Contract, if this Contract is not funded, then both parties are relieved of all of their obligations under this Contract. The INSTITUTE acknowledges and agrees that the Project is a multiyear project subject to Tex. Health & Safety Code, Ch. 102, Section 102.257.

Section 2.13 Confidentiality of Documents and Information. In connection with work contemplated for the Project or pursuant to complying with various provisions of this Contract, the RECIPIENT may disclose its confidential business, financial, technical, scientific information and other information to the INSTITUTE ("Confidential Information"). To assist the INSTITUTE in identifying such information, the RECIPIENT shall mark or designate the information as "confidential," provided however that the failure to so designate does not operate as a waiver to protections provided by applicable law or this Contract. The INSTITUTE shall use no less than reasonable care to protect the confidentiality of the Confidential Information to the fullest extent permissible under the Texas Public Information Act, Texas Government Code, Chapter 552 (the "**TPIA**"), and, except as otherwise provided in the TPIA to prevent the disclosure of the Confidential Information to third parties for a period of time equal to three (3) years from the termination of the contract, unless the INSTITUTE and the RECIPIENT agree in writing to extend such time period, provided that this obligation shall not apply to information that:

(a) was in the public domain at the time of disclosure or later became part of the public domain through no act or omission of the INSTITUTE in breach of this Contract;

(b) was lawfully disclosed to the INSTITUTE by a third party having the right to disclose it without an obligation of confidentiality;

(c) was already lawfully known to the INSTITUTE without an obligation of confidentiality at the time of disclosure;

(d) was independently developed by the INSTITUTE without using or referring to the RECIPIENT's Confidential Information; or

(e) is required by law or regulation to be disclosed.

The INSTITUTE shall hold the Confidential Information in confidence, shall not use such Confidential Information except as provided by the terms of this Contract, and shall not disclose such Confidential Information to third parties without the prior written approval of the RECIPIENT or as otherwise allowed by the terms of the Contract. Subject in all respects to the terms of this Contract and the TPIA, the INSTITUTE has the right to use and disclose the Confidential Information reasonably in connection with the exercise of its rights under the Contract.

In the event that the INSTITUTE is requested or required (by oral questions, interrogatories, requests for information or documents in legal proceedings, subpoena, civil investigative demand or other similar process by a court of competent jurisdiction or by any administrative, legislative, regulatory or self-regulatory authority or entity) to disclose any Confidential Information, the INSTITUTE shall provide the RECIPIENT with prompt written notice of any such request or requirement so that the RECIPIENT may seek a protective order or other appropriate remedy. If, in the absence of a protective order or other remedy, the INSTITUTE is nonetheless legally compelled to make any such disclosure of Confidential Information to any person, the INSTITUTE may, without liability hereunder, disclose only that portion of the Confidential Information that is

legally required to be disclosed, provided that the INSTITUTE will use reasonable efforts to assist the RECIPIENT, at the RECIPIENT's expense, in obtaining an appropriate protective order or other reliable assurance that confidential treatment will be accorded the Confidential Information. To the extent that such Confidential Information does not become part of the public domain by virtue of such disclosure, it shall remain Confidential Information hereunder.

Article III
DISBURSEMENT OF GRANT AWARD PROCEEDS

Section 3.01 Payment of Grant Award Proceeds. The INSTITUTE will advance Grant award proceeds upon request by the RECIPIENT, consistent with the amounts and schedule as provided in Attachment B. If the RECIPIENT does not request or the Oversight Committee does not authorize advancement of funds for some or the entire Grant award proceeds, disbursement of Grant award proceeds for services performed and allowable expenses and costs incurred pursuant to the Scope of Work will be on a reimbursement basis. To the extent that completion of certain milestones is associated with a specific tranche of funding as reflected in the Scope of Work, those milestones shall be accomplished before funding may be provided for next tranche of funding. The INSTITUTE reserves the right to terminate the Contract should a key milestone not be met.

Section 3.02 Requests for Reimbursement and Quarterly Financial Status Reports. If the RECIPIENT does not receive an advance disbursement of Grant proceeds, the RECIPIENT's requests for reimbursement shall be made on INSTITUTE Form 269a (Financial Status Report). If the RECIPIENT has elected to receive an advance disbursement of Grant proceeds, RECIPIENT shall submit INSTITUTE Form 269a (Financial Status Report) to document all costs and allowable expenses paid with Grant proceeds. The RECIPIENT shall submit the INSTITUTE Form 269a quarterly to the INSTITUTE within 90 days following the end of the quarter covered by the bill. A final INSTITUTE Form 269a shall be submitted by RECIPIENT not later than 90 days after the Termination Date. An extension of time for submission deadlines specified herein must be expressly authorized in writing by the INSTITUTE.

Section 3.03 Actual Costs and Allowable Expenses. Because the Approved budget for the Project(s) as set forth in Attachment B is only an estimate, the parties agree that the RECIPIENT's billings under this Contract will reflect the actual costs and expenses incurred in performing the Project(s), regardless of the Approved Budget, up to the total contracted amount specified in Section 2.01 "Award of Monies." The RECIPIENT shall use Grant proceeds only for allowable expenses consistent with state law and agency administrative rules. Allowable expenses for the Project(s) shall be only as outlined in the Approved Budget and any modifications to same.

Section 3.04 Travel Expenses. Reimbursement for travel expenditures shall be in accordance with the Approved Budget. Prior written approval from the INSTITUTE must be obtained before travel that exceeds the amount included in the Approved Budget commences. Failure to obtain such prior written approval shall result in such excess travel costs constituting expenses that may not be taken into account for the purposes of calculating expenditure of Grant funds under this Contract.

Section 3.05 Budget Modifications. The total Approved Budget and the assignment of costs may be adjusted based on implementation of the Scope of Work, spending patterns, and unexpended funds, but only by an amendment to the Approved Budget. In no event shall an amendment to the Approved Budget result in payments in excess of the aggregate amount specified in Section 2.01 "Award of Monies" or in approved supplemental funding for the Project, if any. The RECIPIENT may make transfers between or among lines within budget categories without prior written approval provided that:

(a) The total dollar amount of all changes of any single line item within budget categories (individually and in the aggregate) is less than 10% of the total Approved Budget;

(b) The transfer will not increase or decrease the total Approved Budget;

(c) The transfer will not materially change the nature, performance level, or Scope of Work of the Project; and

(d) The RECIPIENT submits a revised copy of the Approved Budget including a narrative justification of the changes prior to incurring costs in the new category.

All other budget changes or transfers require the INSTITUTE's express prior written approval. Transfer of funds between categories in the Project's Approved Budget may be allowed if requests are in writing, fit within the Scope of Work and the total Approved Budget, are beneficial to the achievement of the objectives of the Project, and appear to be an efficient, effective use of the INSTITUTE's funds.

Section 3.06 Withholding Payment. The INSTITUTE may withhold Grant award proceeds from RECIPIENT if required Financial Status Reports (Form 269a) are not on file for previous quarters or for the final period, if material program requirements are not met and remain uncured after a reasonable time period to cure, if the RECIPIENT is in breach of any material term of this Contract, or in accordance with provisions of this Contract as well as applicable state or federal laws, regulations or administrative rules, and the breach remains uncured after a reasonable time period to cure. The INSTITUTE shall have the right to withhold all or part of any future payments to the RECIPIENT to offset any prior advance payments made to the RECIPIENT for ineligible expenditures that have not been refunded to the INSTITUTE by the RECIPIENT.

Section 3.07 Grant Funds as Supplement to Budget. The RECIPIENT shall use the Grant proceeds awarded pursuant to this Contract to supplement its overall budget. These funds will in no event supplant existing funds currently available to the RECIPIENT that have been previously budgeted and set aside for the Project. The RECIPIENT will not bill the INSTITUTE for any costs under this Contract that also have been billed or should have been billed to any other funding source.

Section 3.08 **Buy Texas**. The RECIPIENT shall apply good faith efforts to purchase goods and services from suppliers in Texas to the extent reasonably possible, to achieve a goal of more than 50 percent of such purchases from suppliers in Texas.

Section 3.09 **Historically Underutilized Businesses**. The RECIPIENT shall use reasonable efforts to purchase materials, supplies or services from a Historically Underutilized Business (HUB). The Texas Procurement and Support Services website will assist in finding HUB vendors (http://www.window.state.tx.us/procurement.) The RECIPIENT shall complete a HUB report with each annual report submitted to the INSTITUTE in accordance with Attachment E.

Section 3.10 **Limitation on Use of Grant Award Proceeds to Pay Indirect Costs**. The RECIPIENT shall not spend more than five percent of the Grant award proceeds for Indirect Costs.

Section 3.11 **Carry Forward of Unspent Funds and No Cost Extension**. RECIPIENT may request to carry forward unspent funds into the budget for the next year. Carryover of unspent funds must be specifically approved by the INSTITUTE. The INSTITUTE may approve a no cost extension for the Contract for a period not to exceed six (6) months after the Termination Date if additional time beyond the Termination date is required to ensure adequate completion of the approved project. The Contract must be in good fiscal and programmatic standing. All terms and conditions of the Contract shall continue during any extension period and if such extension is approved, notwithstanding Section 2.03, all references to the "Termination Date" shall be deemed to mean the date of expiration of such extension period.

Article IV
AUDITS AND INSPECTIONS

Section 4.01 **Record Keeping**. The RECIPIENT, each Collaborator whose costs are funded in all or in part by the Grant shall maintain or cause to be maintained books, records, documents and other evidence (electronic or otherwise) pertaining in any way to its performance under and compliance with the terms and conditions of this Contract ("**Records**"). The RECIPIENT, each Collaborator and each Contractor shall use, or shall cause the entity which is maintaining such Records to use generally accepted accounting principles in the maintenance of such Records, and shall retain or require to be retained all of such Records for a period of three (3) years from the Termination Date of the Contract.

Section 4.02 **Audits**. Upon request and with reasonable notice, the RECIPIENT, each Collaborator and each Contractor whose costs are charged to the Project shall allow, or shall cause the entity which is maintaining such items to allow, the INSTITUTE, or auditors working on behalf of the INSTITUTE, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract all of its Records during regular working hours. Acceptance of funds directly under the Contract or indirectly through a subcontract under the Contract constitutes acceptance of the authority of the INSTITUTE, or auditors working on behalf of the INSTITUTE, including the State Auditor and/or the Comptroller

of Public Accounts, to conduct an audit or investigation in connection with those funds for a period of three (3) years from the Termination Date of the Contract.

Notwithstanding the foregoing, any RECIPIENT expending $500,000 or more in federal or state awards during its fiscal year shall obtain either an annual single audit or a program specific audit. A RECIPIENT expending funds from only one state program may elect to obtain a program specific audit in accordance with Office of Management and Budget (OMB) Circular A-133 or with the State of Texas Uniform Grant Management Standards (UGMS). A single audit is required if funds from more than one federal or state program are spent by the RECIPIENT. The audited time period is the RECIPIENT's fiscal year, not the INSTITUTE funding period.

Section 4.03 Inspections. In addition to the audit rights specified in Section 4.02 "Audits", the INSTITUTE shall have the right to conduct periodic onsite inspections within normal working hours and on a day and a time mutually agreed to by the parties, to evaluate the Institute-Funded Activity. The RECIPIENT shall fully participate and cooperate in any such evaluation efforts.

Section 4.04 On-going Obligation to Submit Requested Information. The RECIPIENT shall, submit other information related to the Grant to the INSTITUTE as may be reasonably requested from time-to-time by the INSTITUTE, by the Legislature or by any other funding or regulatory bodies covering the RECIPIENT's activities under this Contract.

Section 4.05 Duty to Resolve Deficiencies. If an audit and/or inspection under this Article IV finds there are deficiencies that should be remedied, then the RECIPIENT shall resolve and/or cure such deficiencies within a reasonable time frame specified by the INSTITUTE. Failure to do so shall constitute an Event of Default pursuant to Section 8.03 "Event of Default." Upon the RECIPIENT'S request, the parties agree to negotiate in good faith, specific extensions so that the RECIPIENT can cure such deficiencies.

Section 4.06 Repayment of Grant Proceeds for Improper Use. In no event shall RECIPIENT retain Grant funds that have not been used by the RECIPIENT for purposes for which the Grant was intended or in violation of the terms of this Contract. The RECIPIENT shall repay any portion of Grant proceeds used by the RECIPIENT for purposes for which the Grant was not intended, as determined by the final results of an audit conducted pursuant to the provisions of this Contract. Unless otherwise expressly provided for in writing and appended to this Contract, the repayment shall be made to the INSTITUTE no later than forty-five (45) days upon a written request by the INSTITUTE specifying the amount to be repaid and detailing the basis upon which such request is being made and the amount shall include interest calculated at an amount not to exceed five percent (5%) annually. The RECIPIENT may request that the INSTITUTE waive the interest, subject in all cases to the INSTITUTE'S sole discretion.

Section 4.07 Repayment of Grant Proceeds for Relocation Outside of Texas. Unless waived by a vote of the Oversight Committee, the RECIPIENT shall repay the INSTITUTE all Grant proceeds disbursed to RECIPIENT in the event that RECIPIENT relocates its principal

place of business outside of the State during the Contract term or within 3 years after the final payment of the Grant funds is made by the INSTITUTE.

Article V
ASSURANCES AND CERTIFICATIONS

Adoption of Attachment C. The INSTITUTE and the RECIPIENT hereby adopt the terms of Attachment C in their entirety, incorporate them as if fully set forth herein, and agree to perform and be bound by all such terms.

Article VI
INTELLECTUAL PROPERTY AND REVENUE SHARING

Adoption of Attachment D. The INSTITUTE and the RECIPIENT hereby adopt the terms of Attachment D in their entirety, incorporate them as if fully set forth herein, and agree to perform and be bound by all such terms.

Article VII
REPORTING

Adoption of Attachment E. The INSTITUTE and the RECIPIENT hereby adopt the terms of Attachment E in their entirety, incorporate them as if fully set forth herein, and agree to perform and be bound by all such terms.

Article VIII
EARLY TERMINATION AND EVENT OF DEFAULT

Section 8.01 Early Termination of Contract. This Contract may be terminated prior to the Termination Date specified in Section 2.03 “Contract Term” by:

(a) Mutual written consent of all parties to this Contract;
or

(b) The INSTITUTE for an Event of Default (defined in Section 8.03) by the RECIPIENT;
or

(c) The INSTITUTE if allocated funds should become legally unavailable during the Contract period and the INSTITUTE is unable to obtain additional funds for such purposes; or

(d) The RECIPIENT for convenience.

Section 8.02 Repayment of Grant Proceeds upon Early Termination. The INSTITUTE may require the RECIPIENT to repay some or all of the disbursed Grant proceeds in the event of early termination under 8.01 (d) above or under Section 8.01(b) above, to the extent such Event of Default resulted from Grant funds being expended in violation of this Contract. To the extent that the INSTITUTE exercises this option, the INSTITUTE shall provide written notice

to the RECIPIENT stating the amount to be repaid, applicable interest calculated not to exceed five percent (5%) annually, and the schedule for such repayment. The RECIPIENT may request that the INSTITUTE waive the interest, subject in all cases to the INSTITUTE'S sole discretion. In no event shall the RECIPIENT retain Grant funds that have not been used by the RECIPIENT for purposes for which the Grant was intended.

Section 8.03 Event of Default. The following events shall, unless expressly waived in writing by the INSTITUTE or fully cured by the RECIPIENT pursuant to the provisions herein, constitute an event of default (each, an "**Event of Default**"):

(a) The RECIPIENT's failure, in any material respect, to conduct the Project in accordance with the approved Scope of Work and to demonstrate progress towards achieving the milestones set forth in Section 2.02;

(b) The RECIPIENT's failure to conduct the Project within the State of Texas to the extent required under this Contract unless as otherwise specified in the application, Scope of Work or Approved Budget;

(c) The RECIPIENT's failure to fully comply, in any material respect, with any provision, term, condition, covenant, representation, certification, or warranty contained in this Contract or any other document incorporated herein by reference;

(d) The RECIPIENT's failure to comply with any applicable federal or state law, administrative rule, regulation or policy with regard to the conduct of the Project;

(e) The RECIPIENT's material misrepresentation or false covenant, representation, certification, or warranty made by RECIPIENT herein, in the Grant application, or in any other document furnished by RECIPIENT pursuant to this Contract that was misleading at the time that it was made; or

(f) The RECIPIENT ceases its business operations, has a receiver appointed for all or substantially all of its assets, makes a general assignment for the benefit of creditors, is declared insolvent by a court of competent jurisdiction or becomes the subject, as a debtor, of a proceeding under the federal bankruptcy code, which such proceedings are not dismissed within ninety (90) days after filing.

Section 8.04 Notice Required. If the RECIPIENT intends to terminate pursuant to Section 8.01(d) "Early Termination of Contract", it shall provide written notice to the INSTITUTE pursuant to the notice provisions of Section 9.21 "Notices" no later than thirty (30) days prior to the intended date of termination.

If the INSTITUTE intends to terminate for an Event of Default under Section 8.01(b) by the RECIPIENT, as described in Section 8.03 "Event of Default", the INSTITUTE shall provide written notice to the RECIPIENT pursuant to Section 9.21 "Notices" and shall include a reasonable description of the Event of Default and, if applicable, the steps necessary to cure such Event of Default. Upon receiving notice from the INSTITUTE, the RECIPIENT shall have thirty (30) days

beginning on the day following the receipt of notice to cure the Event of Default. Upon request, the INSTITUTE may provide an extension of time to cure the Event of Default(s) beyond the thirty (30) day period specified herein so long as the RECIPIENT is using reasonable efforts to cure and is making reasonable progress in curing such Event(s) of Default. The extension shall be in writing and appended to the Contract. If the RECIPIENT is unable or fails to timely cure an Event of Default, unless expressly waived in writing by the INSTITUTE, this Contract shall immediately terminate as of the close of business on the final day of the allotted cure period without any further notice or action by the INSTITUTE required. **In addition, and notwithstanding the foregoing, the INSTITUTE and the RECIPIENT agree that certain events that cannot be cured shall, unless expressly waived in writing by the INSTITUTE, constitute a final Event of Default under this Contract and this Contract shall terminate immediately upon the INSTITUTE giving the RECIPIENT written "Notice of Event of Default and FINAL TERMINATION."**

In the event that the INSTITUTE terminates the Contract under Section 8.01(c) above because allocated funds become legally unavailable during the Contract period, the INSTITUTE shall immediately provide written notification to the RECIPIENT of such fact pursuant to Section 9.21 "Notices." The Contract is terminated upon the RECIPIENT's receipt of that notification, subject to Section 9.09 "Survival of Terms."

Section 8.05 Duty to Report Event of Default. The RECIPIENT shall notify the INSTITUTE in writing pursuant to Section 9.21 "Notices", promptly and in no event more than (30) days after it obtains knowledge of the occurrence of any Event of Default. The RECIPIENT shall include a statement setting forth reasonable details of each Event of Default and the action which the RECIPIENT proposes to take with respect thereto.

Section 8.06 Obligations/Liabilities Affected by Early Termination. The RECIPIENT shall not incur new obligations that otherwise would have been paid for using Grant funds after the receipt of notice as provided by Section 8.04 "Notice Required", unless expressly permitted by the INSTITUTE in writing, and shall cancel as many outstanding obligations as possible. The INSTITUTE shall not owe any fee, penalty or other amount for exercising its right to terminate the Contract in accordance with Section 8.01. In no event shall the INSTITUTE be liable for any services performed, or costs or expenses incurred, after the Termination Date of the Contract. Early termination by either party shall not nullify obligations already incurred, including the RECIPIENT's revenue sharing obligations as set forth in Attachment D, or the performance or failure to perform obligations prior to the Termination Date.

Section 8.07 Interim Remedies. Upon receipt by the RECIPIENT of a notice of Event of Default, and at any time thereafter until such Event of Default is cured to the satisfaction of the INSTITUTE or this Contract is terminated, the INSTITUTE may enforce any or all of the following remedies (such rights and remedies being in addition to and not in lieu of any rights or remedies set forth herein):

(a) The INSTITUTE may refrain from disbursing any amount of the Grant funds not previously disbursed; provided, however, the INSTITUTE may make such a

disbursement after the occurrence of an Event of Default without thereby waiving its rights and remedies hereunder;

(b) The INSTITUTE may enforce any additional remedies it has in law or equity.

The rights and remedies herein specified are cumulative and not exclusive of any rights or remedies that the INSTITUTE would otherwise possess.

Article IX
MISCELLANEOUS

Section 9.01 Uniform Grant Management Standards. Unless otherwise provided herein, the RECIPIENT agrees that the Uniform Grant Management Standards (UGMS), developed by the Governor's Budget and Planning Office as directed under the Uniform Grant Management Act of 1981, TEX. GOVT. CODE, Ch. 783, apply as additional terms and conditions of this Contract and that the standards are adopted by reference in their entirety. If there is a conflict between the provisions of this Contract and UGMS, the provisions of this Contract will prevail unless expressly stated otherwise.

Section 9.02 Management and Disposition of Equipment. During the term of this Contract, the RECIPIENT may use Grant funds to purchase Equipment to be used for the authorized purpose of the Project, subject to the conditions set forth below. Unless otherwise provided herein, title to Equipment shall vest in the RECIPIENT upon termination of the Contract.

(a) The INSTITUTE must authorize the acquisition in advance and in writing but an acquisition is deemed authorized if included in the Approved Budget for the Project;

(b) Equipment purchased with Grant funds must stay within the State of Texas;

(c) Equipment purchased with Grant funds must be materially deployed to the uses and purposes related to the Project;

(d) In the event the RECIPIENT is indemnified, reimbursed or otherwise compensated for any loss of, destruction of, or damage to the Equipment purchased using Grant funds, it shall use the proceeds to repair or replace said Equipment;

(e) Equipment may be exchanged (trade-in) or sold without the prior written approval of the INSTITUTE if the proceeds thereof shall be applied to the acquisition cost of replacement Equipment;

(f) The RECIPIENT may use its own property management standards and procedures provided that it observes the terms of UGMS, A-102, in all material respects;

(g) The title or ownership of the Equipment shall not be encumbered for purposes other than the Project nor or transferred other than to a permitted assignee of this Contract, without the prior written approval of the INSTITUTE;

(h) If the original or replacement Equipment is no longer needed for the originally authorized purpose or for other activities supported by the INSTITUTE, the RECIPIENT shall request disposition instructions from the INSTITUTE and, upon receipt, shall fully comply therewith; and

(i) If this Contract is terminated early pursuant to Section 8.01(b), (d), (e), or (f) above, the INSTITUTE shall determine the final disposition of Equipment purchased with Grant award money.

Section 9.03 Supplies and Other Expendable Property. The RECIPIENT shall classify as materials, supplies and other expendable property the allowable unit acquisition cost of such property under $5,000 necessary to carry out the Project. Title to supplies and other expendable property shall vest in the RECIPIENT upon acquisition.

Section 9.04 Acknowledgement of Grant Funding and Publicity. The parties agree to the following terms and conditions regarding acknowledging Grant funding and publicity:

(a) The parties agree to fully cooperate and coordinate with each other in connection with all press releases and publications regarding the award of the Grant, the execution of the Contract and the Institute-Funded Activities.

(b) The RECIPIENT shall notify the INSTITUTE's Information Specialist or similar personnel at least three business days prior to any press releases, advertising, publicity, use of CPRIT logo, or other promotional activities that pertain to the Project or any Institute-Funded Activity. In the event that the INSTITUTE wishes to participate in a joint press release, the RECIPIENT shall coordinate and cooperate with the INSTITUTE's Information Specialist or similar personnel to develop a mutually agreeable joint press release.

(c) Consistent with the goal of encouraging development of scientific breakthroughs and dissemination of knowledge, publication or presentation of scholarly materials is expected and encouraged. The RECIPIENT may publish in scholarly journals or other peer-reviewed journals (including graduate theses and dissertations) and may make presentations at scientific meetings without prior notice to or consent of the INSTITUTE, except as may otherwise be set forth in this Contract. The RECIPIENT shall promptly notify the INSTITUTE when any scholarly presentations or publications have been accepted for public disclosure and shall provide the INSTITUTE with final copies of all such accepted presentations and publications. The RECIPIENT shall acknowledge receipt of the INSTITUTE funding in all publications, presentations, press releases and other materials regarding the work associated with the Institute-Funded Activities. The

RECIPIENT shall promptly submit an electronic version of all published manuscripts to PubMed Central in accordance with Section 9.05 "Public Access to Research Results."

(d) When grant funds are used to prepare print or visual materials for educational or promotional purposes for the general public (e.g., patients), and excluding presentations and publications discussed above in subsection (c), the RECIPIENT shall provide a copy of such materials to the INSTITUTE at least ten (10) days prior to printing. The RECIPIENT shall also acknowledge receipt of the INSTITUTE funding on all such materials including, but not limited to, brochures, pamphlets, booklets, training fliers, project websites, videos and DVDs, manuals and reports, as well as on the labels and cases for audiovisual or videotape/DVD presentations.

Section 9.05 Public Access to Results of Institute-Funded Activities. The RECIPIENT shall submit an electronic version of its final peer-reviewed journal manuscripts that arise from Grant funds to the digital archive National Library of Medicine's PubMed Central upon acceptance for publication. These papers must be accessible to the public on PubMed no later than 12 months after publication. This policy is subject to the terms of Attachment D and does not supplant applicable copyright law. For clarity, this policy is not intended to require the RECIPIENT to make a disclosure at a time or in any manner that would cause the RECIPIENT to abandon, waive or disclaim any intellectual property rights that it is obligated to protect pursuant to the terms of Attachment D.

Section 9.06 Work to be Conducted in State. The RECIPIENT agrees that it will use reasonable efforts to direct that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing that is part of or relating to any Institute-Funded Activities take place in the State of Texas, including the establishment of facilities to meet this purpose. If the RECIPIENT decides not to conduct such work in the State of Texas, the RECIPIENT shall provide a prior written explanation to the INSTITUTE detailing the RECIPIENT'S reasons for conducting the work outside of the State of Texas and the RECIPIENT's efforts made to conduct the work in the State of Texas.

Section 9.07 Duty to Notify. During the term of this Contract and for a period of five (5) years thereafter, the RECIPIENT is under a continuing obligation to notify the INSTITUTE's Chief Executive Officer at the same time it is required to notify any Federal or State entity of any unexpected adverse event or condition that materially impacts the performance or general public perception of the conduct or results of the Project and Institute-Funded Activities, including any impact to the Scope of Work included in the Contract and events or results that have a serious adverse impact on human health, safety or welfare. By way of example only, if clinical testing of the results of Institute-Funded Activities reveal an unexpected risk of developing serious health conditions or death, then the RECIPIENT shall, at the same time it notifies any Federal or State entity, promptly so notify the INSTITUTE's Chief Executive Officer even if such results are not available until after the term of this Contract. Notice required under this section shall be made as promptly as reasonably possible and shall follow the procedures set forth in Section 9.21 "Notices."

Section 9.08 Severability. If any provision of this Contract is construed to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or enforceability shall not affect any other provisions hereof. The invalid, illegal or unenforceable provision shall be deemed stricken and deleted to the same extent and effect as if never incorporated herein. All other provisions shall continue as provided in this Contract.

Section 9.09 Survival of Terms. Termination or expiration of this Contract for any reason will not release either party from any liabilities or obligations set forth in this Contract that: (1) the Parties have expressly agreed shall survive any such termination or expiration; or (2) remain to be performed or by their nature would be intended to be applicable following any such termination or expiration. Such surviving terms include, but are not limited to, Sections 2.13, 4.01, 4.02, 4.05, 4.06, 8.02, 8.06, 9.04, 9.05, 9.06, 9.07, 9.09, 9.14, 9.15, 9.16, 9.17, 9.18, and Attachment D.

Section 9.10 Binding Effect and Assignment or Modification. This Contract and all terms, provisions and obligations set forth herein shall be binding upon and shall inure to the benefit of the parties and their successors and permitted assigns, including all other state agencies and any other agencies, departments, divisions, governmental entities, public corporations or other entities which shall be successors to either of the parties or which shall succeed to or become obligated to perform or become bound by any of the covenants, agreements or obligations hereunder of either of the parties hereto. Upon a permitted assignment of this Contract by RECIPIENT, all references to "the RECIPIENT" herein shall be deemed to refer to such permitted assignee.

Section 9.11 No Waiver of Contract Terms. Neither the failure by the RECIPIENT or the INSTITUTE, in any one or more instances, to insist upon the complete and total observance or performance of any term or provision hereof, nor the failure of the RECIPIENT or the INSTITUTE to exercise any right, privilege or remedy conferred hereunder or afforded by law, shall be construed as waiving any breach of such term or provision or the right to exercise such right, privilege or remedy thereafter. In addition, no delay on the part of either the RECIPIENT or the INSTITUTE, in exercising any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude other or further exercise thereof or the exercise of any other right or remedy.

Section 9.12 No Waiver of Sovereign Immunity. No provision of this Contract is in any way intended to constitute a waiver by the INSTITUTE, the RECIPIENT (if applicable), or the State of Texas of any immunities from suit or from liability that the INSTITUTE, the RECIPIENT, or the State of Texas may have by operation of law.

Section 9.13 Force Majeure. Neither the INSTITUTE nor the RECIPIENT will be liable for any failure or delay in performing its obligations under the Contract if such failure or delay is due to any cause beyond the reasonable control of such party, including, but not limited to, unusually severe weather, strikes, natural disasters, fire, civil disturbance, epidemic, war, court order or acts of God. The existence of such causes of delay or failure will extend the period of performance in the exercise of reasonable diligence until after the causes of delay or failure have

been removed. Each party must inform the other in accordance with Section 9.21 "Notices" within five (5) business days, or as soon as it is practical, of the existence of a force majeure event or otherwise waive this right as a defense.

Section 9.14 Disclaimer of Damages. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, PUNITIVE, EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES. THIS LIMITATION WILL APPLY REGARDLESS OF WHETHER OR NOT THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Section 9.15 Indemnification and Hold Harmless. Except as provided herein, the RECIPIENT agrees to fully indemnify and hold the INSTITUTE and the State of Texas harmless from and against any and all claims, demands, costs, expenses, liabilities, causes of action and damages of every kind and character (including reasonable attorneys fees) which may be asserted by any third party in any way related or incident to, arising out of, or in connection with (1) the RECIPIENT's negligent, intentional or wrongful performance or failure to perform under this Contract, (2) the RECIPIENT's receipt or use of Grant funds, or (3) any negligent, intentional or wrongful act or omission committed by the RECIPIENT as part of an Institute-Funded Activity or during the Project. In addition, the RECIPIENT agrees to fully indemnify and hold the INSTITUTE and the State of Texas harmless from and against any and all costs and expenses of every kind and character (including reasonable attorneys fees, costs of court and expert fees) that are incurred by the INSTITUTE or the State of Texas arising out of or related to a third party claim of the type specified in the preceding sentence. Notwithstanding the preceding, such indemnification shall not apply in the event of the sole or gross negligence of the INSTITUTE. If the RECIPIENT is a State of Texas agency or institution of higher education, then this Section 9.15 is subject to the extent authorized by the Texas Constitution and the laws of the State of Texas.

The RECIPIENT acknowledges and agrees that this indemnification shall apply to, but is not limited to, employment matters, taxes, personal injury, and negligence.

It is understood and agreed that it is not the intent of the parties to expand or increase the liability of the State of Texas under this Article. This provision is intended to prevent the RECIPIENT, the INSTITUTE and the State of Texas from attempting or appearing to assume liability it does not have the statutory or legal power to assume.

Section 9.16 Alternative Dispute Resolution. If applicable, the dispute resolution process provided for in TEX. GOVT. CODE, Ch. 2260 shall be used, as further described herein, to resolve any claim for breach of contract made against the INSTITUTE (excluding any uncured Event of Default). The submission, processing and resolution of a party's claim are governed by the published rules adopted by the Attorney General pursuant to TEX. GOVT. CODE, Ch. 2260, as currently effective, hereafter enacted or subsequently amended.

Section 9.17 Applicable Law and Venue. This Contract shall be construed and all disputes shall be considered in accordance with the laws of the State of Texas, without regard to its principles governing the conflict of laws. Provided that the RECIPIENT first complies with

procedures set forth in Section 9.16 "Alternative Dispute Resolution," exclusive venue and jurisdiction for the resolution of claims arising from or related to this Contract shall be in the federal and state courts in Travis County, Texas.

Section 9.18 Attorneys' Fees. In the event of any litigation, appeal or other legal action to enforce any provision of the Contract, the RECIPIENT shall pay all expenses of such action, including attorneys' fees and costs, if the INSTITUTE is the prevailing party. If the RECIPIENT is a State of Texas agency or institution of higher education, then this Section 9.18 is subject to the extent authorized by the Texas Constitution and the laws of the State of Texas.

Section 9.19 Counterparts. This Contract may be executed in any number of counterparts, each of which when so executed and delivered shall be an original, but such counterparts shall together constitute one and the same instrument.

Section 9.20 Construction of Terms The headings used in this Contract are inserted only as a matter of convenience and for reference and shall not affect the construction or interpretation of this Contract. Where context so indicates, a word in the singular form shall include the plural, a word in the masculine form the feminine, and vice-versa. The word "including" and similar constructions (such as "includes", "included", "for example", "such as", and "e.g.") shall mean "including, without limitation" throughout this Contract. The words "and" and "or" are not intended to convey exclusivity or nonexclusivity except where expressly indicated or where the context so indicates in order to give effect to the intent of the parties.

Section 9.21 Notices. All notices, requests, demands and other communications will be in writing and will be deemed given on the date received as demonstrated by (i) a courier's receipt or registered or certified mail return receipt signed by the party to whom such notice was sent, provided that such notice was sent to the Authorized Signing Official (ASO) at the address provided in the CPRIT Grants Management System, (ii) a fax confirmation page showing that such fax was successfully transmitted to the fax number provided in the CPRIT Grants Management System, or (iii) via correspondence in the CPRIT Grants Management System.

Attachment A

[*****]

ATTACHMENT B

[*****]

ATTACHMENT C

[*****]

ATTACHMENT D

[*****]

ATTACHMENT E

REPORTING REQUIREMENTS

This Attachment E is hereby incorporated into and made a part of that certain **CANCER RESEARCH GRANT CONTRACT** ("**Contract**") by and between the Cancer Prevention and Research Institute of Texas ("**CPRIT**" or the "I**NSTITUTE**") and the RECIPIENT. A capitalized term used in this Attachment shall have the meaning given to term in the Contract or in the Attachments to the Contract, unless otherwise defined herein. In the event of a conflict between the provisions of this Attachment and the provisions of the Contract, this Attachment shall control.

INSTITUTE and RECIPIENT agree as follows:

ANNUAL REPORTING

Section E1.01 Annual Reports. The RECIPIENT shall submit reports annually to the INSTITUTE within 60 days of the anniversary of the Effective Date of this Contract or at such other time as may be specified herein. The reports shall be submitted by the means and in the form(s) required by the INSTITUTE and shall be signed by the Principal Investigator/Program Director and the RECIPIENT's Authorized Signing Official. To the extent possible, the reports shall only include information that may be shared publicly. However, if it is necessary to submit information in the reports that the RECIPIENT considers confidential in order to fully comply with the terms of this Contract, then the RECIPIENT shall use reasonable efforts to mark such information as "confidential" and shall, to the extent practicable, to segregate such information within the reports to facilitate its redaction should redaction ever be necessary or appropriate.

Section E1.02 Contents of Reports. Each report shall contain a signed verification (electronic signature is acceptable) of RECIPIENT's compliance with each of its obligations as set forth in the Contract and shall include the following for the period covered by such report, as may then be applicable:

(a) Project Data. During the term of the Contract, RECIPIENT shall include in its annual report each of the following (except that the final annual report due under this part (a) shall be due within ninety (90) days after the end of the term of the Contract):

(1) A brief statement of the progress made to under the Scope of Work, including the progress to achieve the Project Goals and Timelines set forth in Attachment A.
(2) A brief statement of the Project Goals for the twelve months following submission of the report.
(3) New jobs created in the preceding twelve month period as a result of the Grant funds awarded to RECIPIENT.
(4) An inventory of the Equipment purchased for the Project using Grant funds.
(5) A HUB report in accordance with Section 3.08 "Historically Underutilized Businesses" of the Contract.

(b) Commercialization Data. During the term of the Contract and continuing thereafter for so long as RECIPIENT has ongoing obligations to the INSTITUTE with respect to protection, development, commercialization and licensing of Project Results pursuant to Attachment D, RECIPIENT shall provide information about commercialization activities in a format specified by the INSTITUTE.

(c) Revenue Sharing Data. During the term of the Contract and continuing thereafter for so long as RECIPIENT has ongoing obligations to the INSTITUTE with respect to revenue sharing pursuant to Attachment D:

(1) A statement of the identities of the funding sources, amounts and dates of funding for all funding sources for the Project.

(3) A brief statement of the RECIPIENT's efforts to secure additional funds to support the Project.

(4) All financial information necessary to verify the calculation of the revenue sharing amounts specified in Attachment D.

(d) Additional Data. In addition to the foregoing, RECIPIENT shall use commercially reasonable efforts to also promptly report any other information required by this Contract or otherwise reasonably requested by the INSTITUTE, the Legislature, or any other funding or regulatory bodies covering the RECIPIENT's activities under this Contract.

Section E1.03 Record Keeping and Audits. The provisions of Article IV of the Contract shall apply fully to all information reported to the INSTITUTE pursuant to this Attachment, except that the right of the State of Texas to audit and the RECIPIENT's obligation to maintain Records shall continue until four years after the date of each such report made by RECIPIENT hereunder.

Section E1.04 Confidentiality of Documents and Information. The provisions of Section 2.13 "Confidentiality of Documents and Information" of the Contract shall apply fully to all Confidential Information reported, delivered or submitted to the INSTITUTE pursuant to this Attachment E.

CANCER PREVENTION & RESEARCH

INSTITUTE OF TEXAS

Approved Contract Documents

Title	Approved By	Approved Date
Product Development Base Contract	Jasuja, Rahul	27 Jan 2017
Attachment A - Goals and Objectives	Nelson, Lisa	12 Apr 2017
Attachment B - Verification Request of Contract Document	Jasuja, Rahul	11 Apr 2017
Attachment C Part 1 - Assurances and Certifications	Jasuja, Rahul	27 Jan 2017
Attachment C Part 2 - Matching Compliance Certification	Azeez, Ralph	17 Apr 2017
Attachment D - Intellectual Property and Revenue Sharing	Jasuja, Rahul	18 Oct 2016
Attachment E - Reporting Requirements	Jasuja, Rahul	18 Oct 2016
Chief Executive Officer Approval	Roberts, Wayne	20 Apr 2017

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS EXHIBIT MARKED BY [***] HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

ASSIGNMENT AND ASSUMPTION AGREEMENT
(UMC-131, UMF:-139)

ASS1GNMENT AND ASSUMPTION AGREEMENT (the " **Agreement**"), dated as of June 26, 2009, by and among HEAT BIOLOGICS, INC., a Delaware corporation ("HEAT BIOLOGICS"), HEAT BIOLOGICS II, INC., a Delaware corporation ("HEAT II") and for the limited purpose set forth on the signature page hereto, the University of Miami, a Florida not-for-profit corporation ("UNI VERSITY").

WITNESSETH:

WHEREAS, HEAT BIOLOGICS and UNIVERSITY are parties to a License Agreement effective as of July 11, 2008, (the "**License Agreement**") and Amendment thereto dated April 29, 2009, (the " **License Amendment**"), (collectively referred to as "License Agreements"), relating to the technology and product currently identified as the Podack Antibody Technology (**UMC-131, UME-139**); and

WHEREAS, UNIVERSITY and HEAT BIOLOGICS entered into that certain Stockholders Agreement dated the 11 th day of July, 2008, together with the University of Miami Investor Rights Agreement effective July 11, 2008, and the Common Stock Subscription Agreement dated July 1, 2008, granting to UNIVERSITY certain stock ownership rights together with rights to participate in future stock offerings by HEAT BIOLOGICS (hereinafter collectively referred to as the "Stock Agreements"); and

WHEREAS, UNIVERSITY is the owner and holder of [*****] of all issued and outstanding common stock of-HEAT BIOLOGICS in each class and series on a fully-diluted basis, together with fully-dilutable common shares equal to [*****] of the total number of HEAT BIOLOGICS common shares in each class and series issued and outstanding, pursuant to the terms and conditions of the License Agreement and License Amendment; and

WHEREAS, HEAT BIOLOGICS has license issue fee obligations to UNIVERSITY, as set forth in sections 5.3 and 8.1 (a) of the License Agreement in the total amount of [*****] dollars, which are due and payable as follows:

a) [*****] dollars obligation past due and outstanding, to wit:
Payable within thirty (30) days or the Effective Date, all or before August 11,2008.

b) [*****] dollars paid within one (1) year of the Effective Date;
and

WHEREAS, HEAT BIOLOGICS has past due and outstanding patent fees and costs obligations to UNIVERSITY in the amount of [*****] dollars pursuant to section 5.1 of the License Agreement; and

WHEREAS, HEAT BIOLOGICS has past due and outstanding license issue fees obligations together with past due and outstanding patent fees and costs obligations to UNIVERSITY pursuant to the License Agreement in the total amount of [*****] dollars; and

WHEREAS, HEAT BIOLOGICS requested, and UNIVERSITY granted all extension of the payment dates for past due and outstanding license issue fees together with past due and outstanding patent fees and costs, and as additional consideration shall pay UNIVERSITY the sum of [*****] dollars, to be due and payable on or before such payment extension date granted by UNIVERSITY; and

WHEREAS, HEAT II, is a corporation duly formed under the laws of the State of Delaware on the 23rd day of April, 2009, and is an active corporation and in good standing; and

WHEREAS, pursuant to the License Agreements, HEAT BIOLOGICS desires to assign to HEAT II all of its rights and obligations under the License Agreements, and HEAT II desires to accept such assignment.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and obligations hereinafter set forth, the Parties hereto, intending to be legally bound, hereby agree as follows:

1) **Recitals**. The Parties mutually agrees that the above recitals are true and correct, and are hereby incorporated by reference to this Agreement.

2) **Assignment and Assumption**.

(a) Effective immediately upon execution of this Agreement by all of the parties hereto, HEAT BIOLOGICS sells, transfers, assigns, conveys, grants and sets over to HEAT II, its successors and assigns forever, all of HEAT BIOLOGICS' rights, title and interest as of such date in and to all and any of HEAT BIOLOGICS' rights and obligations under, pursuant to and arising out of the License Agreements, as fully and entirely as the same would have been held and enjoyed by HEAT II as if this assignment had not been made, and

(b) HEAT II accepts, assumes, takes over and succeeds to all of HEAT BIOI.OGICS' rights, title and interest as of such date in and to all and any of the HEAT BIOLOGICS' rights and obligations under, pursuant to and arising out of the License Agreements, and HEAT II covenants and agrees to discharge, perform and comply with, and to be bound by, all the terms, conditions, provisions, obligations, covenants and duties of HEAT BIOLOGICS in connection with all and any of HEAT BIOLOGICS' rights and obligations under, pursuant to and arising out of the License Agreements, as the same may be amended from time to time, (in each case, whether or not any of it relates to the period before or after the date hereof), as if HEAT II were an original party thereto.

3) **Successors**. This Agreement shall he fully binding upon and enforceable with respect to the parties, and their respective representatives, successors, partners, executors, and assigns.

4) **Authority**. Each of the parties hereto represents to the other that (a) it has the corporate or other requisite power and authority to execute, deliver and perform this Agreement, (b) the execution, delivery and performance of this Agreement by it have been duly authorized by all necessary corporate or other actions, (c) it has duly and validly executed and delivered this Agreement, and (d) this Agreement is a legal, valid and binding obligation, enforceable against it in accordance with its terms subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and general equity principles.

5) **Governing Law**. This Agreement shall be governed by and construed in accordance with the law of the State of Florida, without regard to the conflicts of law rules of such state. In any action or proceeding arising out of or relating to this Agreement (an "Action"), each of the parties hereby irrevocably submits to the exclusive jurisdiction of any federal or state court sitting in Miami-Dade County, Florida, and further agrees that any Action shall be heard and determined in such Florida federal court or in such state court. Each party hereby irrevocably waives, to the fullest extent it may effectively do so, the defense of an inconvenient forum to the maintenance of any Action in Miami-Dade County, Florida.

6) **Severability**. The provisions of this Agreement are severable, and if any part of it is found to be unenforceable, the other paragraphs shall remain fully valid and enforceable.

7) **Execution in Counterparts**. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

HEAT BIOLOGICS, INC., a Delaware corporation

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: President

HEAT BIOLOGICS II, INC., a Delaware corporation

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: President

In accordance with Paragraph 12. of the License Agreement, entitled Assignment, UNIVERSITY hereby consents to the assignment and assumption provided for by this Agreement:

Accepted and Agreed as of the date first set forth above:

UNIVERSITY OF MIAMI

By: /s/ Bart Chernow, M.D.
Name: Bart Chernow, M.D.
Title: Director of UM Innovation
Vice Provost of Technology Advancement

EXHIBIT 21.1

Subsidiaries

Name of Subsidiary	Jurisdiction
Heat Biologics I, Inc	Delaware
Heat Biologics III, Inc.	Delaware
Heat Biologics IV, Inc.	Delaware
Heat Biologics GmbH.	Germany
Heat Biologics Australia Pty LTD	Australia
Zolovax, Inc.	Delaware
Pelican Therapeutics, Inc.	Delaware
Skunkworx Bio, Inc.	Delaware
Scorpion Biological Services, Inc.	Delaware
Abacus Biotech, Inc.	Delaware
Blackhawk Bio, Inc.	Delaware
Heat Acquisition Sub, Inc.	Delaware

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

Heat Biologics, Inc.
Morrisville, North Carolina

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-224039 and No. 333-234105), Form S-3 (No. 333-214868, No. 333-237808, No. 333-251255, No. 333-251256 , and No. 333-257051) and Form S-8 (No. 333-193453, No. 333-196763, No. 333-207108, No. 333-213133, No. 333-219238, No. 333-227699, No. 333-233352, No. 333-237137, No. 333-249466, and No. 333-260120) of Heat Biologics, Inc. of our report dated March 25, 2021, relating to the consolidated financial statements which appears in this Form 10-K.

/s/ BDO USA, LLP

BDO USA, LLP
Raleigh, NC

March 11, 2022

EXHIBIT 31.1

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

I, Jeffrey Wolf, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 11, 2022

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

EXHIBIT 31.2

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

I, William Ostrander, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 11, 2022

By: /s/ William L. Ostrander
Name: William L. Ostrander
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

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

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

(1) the accompanying Annual Report on Form 10-K of the Registrant for the year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 11, 2022

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

EXHIBIT 32.2

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

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

(1) the accompanying Annual Report on Form 10-K of the Registrant for the year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 11, 2022

By: /s/ William L. Ostrander
Name: William L. Ostrander
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)