

HEAT BIOLOGICS, INC.
Form 424B4
May 04, 2018

Filed pursuant to Rule 424(b)(4)

File No. 333-224039

PROSPECTUS

3,000,000 Shares of Common Stock

Pre-Funded Warrants to Purchase 9,500,000 Shares of Common Stock

Common Warrants to Purchase 6,250,000 Shares of Common Stock

We are offering 3,000,000 shares of our common stock together with a number of common warrants to purchase 6,250,000 shares of our common stock (and the shares of common stock that are issuable from time to time upon exercise of the common warrants). Each common warrant is exercisable at a price of \$1.584. We are also offering 9,500,000 pre-funded warrants to each purchaser whose purchase of shares of common stock and the common warrant in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering. Subject to limited exceptions, a holder of pre-funded warrants will not have the right to exercise any portion of its pre-funded warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each pre-funded warrant will be exercisable for one share of our common stock. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants and any common warrants sold in this offering.

The purchase price of each pre-funded warrant will equal the price per share at which shares of common stock are being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant will equal \$0.01 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. Each pre-funded warrant is being sold together with a common warrant with the same terms as the common warrant accompanying the common stock. Because a common warrant is being sold together in this offering with each share of common stock and, in the alternative, each pre-funded warrant to purchase one share of common stock, the number of common warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold. The common warrants will be exercisable immediately, will expire five years from the date of issuance (subject to the call

option) and we have the option to call the exercise of any or all of the common warrants, from time to time after any 10-consecutive trading day period during which the daily volume weighted average price (the VWAP) of the common stock is not less than 300% of the exercise price for the common warrants in effect for such 10-consecutive trading day period.

The shares of common stock and pre-funded warrants, if any, can each be purchased only with the accompanying common warrants (other than the over-allotment option), but will be issued separately, and will be immediately separable upon issuance.

Our common stock is listed on the NASDAQ Capital Market under the symbol HTBX. On May 2, 2018, the last reported sale price of our common stock on the NASDAQ Capital Market was \$2.48 per share. The public offering price per common share or pre-funded warrant, as the case may be, was determined between us, the underwriter and investors based on market conditions at the time of pricing. The public offering price of the common warrant is \$0.01 per common warrant. There is no established trading market for the pre-funded warrants or common warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the pre-funded warrants or common warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the pre-funded warrants and the common warrants will be limited.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) and, as such, have elected to comply with certain reduced public company reporting requirements. See Prospectus Summary Implications of Being an Emerging Growth Company.

Investing in our securities involves risk. See Risk Factors beginning on page 8 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Per Pre-Funded Warrant	Per Common Warrant	Total
Public offering price ⁽¹⁾	\$ 1.44	\$ 1.43	\$ 0.01	\$ 17,967,500
Underwriting discounts and commissions ⁽²⁾	\$ 0.1008	\$ 0.1001	\$ 0.0007	\$ 1,257,725
Proceeds, before expenses, to us	\$ 1.3392	\$ 1.3299	\$ 0.0093	\$ 16,709,775

(1)

The public offering price is \$1.44 per share of common stock, \$1.43 per pre-funded warrant and \$0.01 per accompanying common warrant.

- (2) We have also agreed to reimburse the underwriters for certain expenses incurred in connection with this offering. See Underwriting beginning on page 46 of this prospectus for a description of the compensation payable to the underwriters.
-

We have granted a 45-day option to the representative of the underwriters to purchase up to 1,875,000 additional shares of common stock and/or additional common warrants to purchase up to 937,500 shares of common stock from us solely to cover over-allotments, if any.

We expect that delivery of the securities offered hereby against payment will be made on or about May 7, 2018.

Sole Book-Running Manager

A.G.P.

Offering Securities Through Euro Pacific Capital Inc.

Co-Manager

CIM Securities, LLC

May 2, 2018

TABLE OF CONTENTS

Description	Page
<u>PROSPECTUS SUMMARY</u>	1
<u>THE OFFERING</u>	4
<u>RISK FACTORS</u>	8
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	28
<u>USE OF PROCEEDS</u>	29
<u>CAPITALIZATION</u>	30
<u>DILUTION</u>	31
<u>MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	32
<u>DIVIDEND POLICY</u>	33
<u>DESCRIPTION OF OUR SECURITIES</u>	34
<u>DESCRIPTION OF SECURITIES WE ARE OFFERING</u>	38
<u>MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK, PRE-FUNDED WARRANTS AND COMMON WARRANTS</u>	41
<u>UNDERWRITING</u>	46
<u>NOTICE TO INVESTORS</u>	48
<u>LEGAL MATTERS</u>	50
<u>EXPERTS</u>	50
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	50
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	51

You should rely only on the information contained in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering. Neither we nor the underwriters have authorized anyone to provide you with information that is different. We are offering to sell, and seeking offers to buy, the securities covered hereby only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities covered hereby. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted. You should also read and consider the information in the documents to which we have referred you under the caption **Where You Can Find Additional Information in the prospectus. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading **Where You Can Find Additional Information**.**

For investors outside the United States: Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities covered hereby and the distribution of this prospectus outside of the United States.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We believe that the data obtained from these industry publications and third-party research, surveys and studies are reliable. We are ultimately responsible for all disclosure included in this prospectus.

Except where the context requires otherwise, in this prospectus the **Company, Heat Biologics, Heat, we, our refer to Heat Biologics, Inc., a Delaware corporation formed in June 2008, and, where appropriate, its wholly owned subsidiaries, Heat Biologics I, Inc., Heat Biologics III, Inc., Heat Biologics IV, Inc., Heat Biologics GmbH and Heat Biologics Australia Pty LTD. and its 80% owned subsidiary, Pelican Therapeutics, Inc.**



PROSPECTUS SUMMARY

The items in the following summary are described in more detail elsewhere in this prospectus and in the documents incorporated by reference herein. This summary highlights selected information contained elsewhere in this prospectus. This summary is not intended to be complete and does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus carefully, especially the Risk Factors section beginning on page 7 and other documents or information included or incorporated by reference in this prospectus before making an investment decision.

Company Overview

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

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

Our Combination Pan-antigen Cytotoxic Therapy (*ComPACT*) is a dual-acting immunotherapy designed to deliver T-cell activation and enhanced, T-cell specific co-stimulation in a single treatment. *ComPACT* helps

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

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

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

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

Clinical Development Plan

Our upcoming milestones for our HS-110 Phase 2 NSCLC, our PTX-35 and our *ComPACT* programs for the next four quarters are set forth below. Anticipated clinical milestones for HS-110 in NSCLC include an interim data readout in Q4 2018 and a final Phase 2 data readout in Q2 2019. Expected PTX-35 milestones include receipt of \$6.9 million in CPRIT grant funds to support the enrollment of the first patient in a Phase 1 clinical trial in Q1 2019 and an interim data readout in Q3 2019. Additionally, we plan on enrolling our first patient in our *ComPACT* trial in Q4 2018 and anticipate an interim data readout in Q2 2019.

Recent Developments

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

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

As predefined in the clinical protocol, patient subgroups were evaluated for levels of tumor infiltrating lymphocytes (TIL) and for PD-L1 checkpoint protein expression on tumor cells. Four of 9 cold tumor patients

with low TIL levels (<10%) at baseline had partial responses. HS-110 also showed a durable effect in patients with low levels of PD-L1, with 3 of 9 patients responding. Both of these patient populations respond poorly to checkpoint inhibitors.

Pursuant to the authority granted to our board of directors by our stockholders at the 2017 Annual Meeting of Stockholders, our board of directors authorized a one-for-ten reverse stock split, which was effected on January 19, 2018. As a result of the stock split, the total number of shares of common stock was reduced to approximately 4.2 million shares for all stockholders of record and the conversion ratio for all instruments convertible into or exercisable for shares of common stock, including stock options and warrants, was proportionately adjusted. The reverse stock split was implemented in order to remain compliant with the NASDAQ Capital Market minimum stock price continued listing requirements. On February 5, 2018, we were notified by the NASDAQ Capital Market that we had regained compliance with the minimum stock price continued listing requirement.

On March 11, 2018, our board of directors declared a dividend of one common share purchase right (a Right) for each outstanding share of our common stock. Each Right initially entitles the registered holder to purchase from us one share of common stock at a price of \$14.00 per share of our common stock, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement, dated as of March 11, 2018, as the same may be amended from time to time (the Rights Agreement), between the Company and Continental Stock Transfer & Trust Company, as 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 acquirer.

General Corporate Information

We were incorporated under the laws of the State of Delaware on June 10, 2008. Our principal offices are located at 801 Capitola Drive, Suite 12, Durham, North Carolina 27713. Our website address is *www.heatbio.com*. We make our periodic and current reports that are filed with the SEC available, free of charge, on our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, and that can be accessed through, our website is not incorporated into and is not a part of this prospectus.

Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the JOBS Act. As an emerging growth company, we intend to take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

.
allowance to provide only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;

.
reduced disclosure about our executive compensation arrangements;

.
no non-binding advisory votes on executive compensation or golden parachute arrangements; and

.

exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you have beneficial ownership.

The Offering

Common stock offered by us

3,000,000 shares of our common stock.

Common warrants offered by us

Common warrants to purchase an aggregate of 6,250,000 shares of our common stock at a purchase price of \$0.01 per common warrant. Each share of our common stock and each pre-funded warrant is being sold together with a common warrant to purchase 0.50 of a share of our common stock. Because a common warrant is being sold together in this offering with each share of common stock and, in the alternative, each pre-funded warrant to purchase one share of common stock, the number of common warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold. Each common warrant will be exercisable immediately, will expire five years from the date of issuance (subject to the call option) and we have the option to call the exercise of any or all of the common warrants, from time to time after any 10-consecutive trading day period during which the daily VWAP of the common stock is not less than 300% of the exercise price for the common warrants in effect for such 10-consecutive trading day period. Each common warrant will have an exercise price per share of \$1.584 (subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events). No fractional shares of common stock will be issued in connection with the exercise of a common warrant. In lieu of fractional shares, we will round up to the next whole share. The common warrants also provide that in the event of a fundamental transaction we are required to cause any successor entity to assume our obligations under the common warrants. In addition, the holder of the common warrant will be entitled to receive upon exercise of the common warrant the kind and amount of securities, cash or property that the holder would have received had the holder exercised the common warrant immediately prior to such fundamental transaction. This prospectus also relates to the offering of the shares of common stock issuable

upon exercise of the common warrants.

Pre-funded warrants offered by us

We are also offering 9,500,000 pre-funded warrants to each purchaser whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded warrants, in lieu of shares of common stock that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the holder, 9.99%) of our outstanding common stock. Subject to limited exceptions, a holder of pre-funded warrants will not have the right to exercise any portion of its pre-funded warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each pre-funded warrant will also be sold with a common warrant. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant will equal the price per share at which the shares of common stock are being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant will be \$0.01 per share. Each pre-funded warrant will be exercisable upon issuance and may be exercised at any time until all of the pre-funded warrants are exercised in full. The pre-funded warrants also provide that in the event of a fundamental transaction we are required to cause any successor entity to assume our obligations under the pre-funded warrants. In addition, the holder of the pre-funded warrant will be entitled to receive upon exercise of the pre-funded warrant the kind and amount of securities, cash or property that the holder would have received had the holder exercised the pre-funded warrant immediately prior to such fundamental transaction. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of such pre-funded warrant. For each pre-funded warrant we sell the number of shares of common stock we are offering will be decreased on a one-for-one basis.

Over-allotment option

We have granted the underwriters a 45-day option to purchase up to 1,875,000 additional shares of our common stock and/or common warrants to purchase up to 937,500 shares of common stock from us at the public offering price less underwriting discounts and commissions.

Common stock to be outstanding after the offering

8,663,919 shares of our common stock. If the underwriters' over-allotment option is exercised in full, the total number of shares of common stock outstanding immediately after this offering would be 10,538,919 (assumes none of the pre-funded warrants and common warrants are exercised). This prospectus also includes the shares of our common stock issuable upon exercise of the pre-funded warrants and common warrants.

Use of Proceeds

We currently intend to use the net proceeds from this offering to fund our and our subsidiaries' preclinical and clinical programs and for working capital and general corporate purposes, including, to acquire, license or invest in complementary businesses, technologies, product candidates or other intellectual property. See Use of Proceeds.

Risk Factors

See the section entitled "Risk Factors" beginning on page 8 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

Market symbol and trading

Our common stock is listed on the NASDAQ Capital Market under the symbol HTBX. There is no established trading market for the pre-funded warrants or common warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the pre-funded warrants or common warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the pre-funded warrants and common warrants will be limited.

The number of shares of common stock shown above to be outstanding after this offering is based on 5,663,919 shares outstanding as of May 2, 2018, and the issuance and sale of 3,000,000 shares of our common stock in this offering at a public offering price of \$1.44 per share.

Unless we indicate otherwise, all information in this prospectus:

.
reflects a one-for-ten reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on January 19, 2018 and the corresponding adjustment of all common stock prices per share and stock option and warrant exercise prices per share and conversion ratios;

.
assumes no exercise by the underwriters of their over-allotment option;

excludes 266,810 shares of our common stock issuable upon exercise of outstanding options under our equity incentive plans at a weighted-average exercise price of \$19.57 per share;

.

excludes 310,397 shares of our common stock reserved for issuance upon the exercise of outstanding warrants with a weighted-average exercise price of \$14.60 per share;

.

assumes no exercise of the common warrants; and

.

excludes 553,196 shares of our common stock that are reserved for equity awards that may be granted under our equity incentive plans.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated financial data as of or for the fiscal years ended December 31, 2017 and 2016 have been derived from our audited consolidated financial statements incorporated by reference in this prospectus. The historical financial data presented below is not necessarily indicative of our financial results in future periods. You should read the summary consolidated financial data together with our consolidated financial statements and the related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations and other information included elsewhere in this prospectus or otherwise incorporated by reference. Our consolidated financial statements are prepared and presented in accordance with U.S. generally accepted accounting principles.

	Year ended December 31,	
	2017	2016
Statement of Operations Data: (in thousands except per share data)		
Revenue	\$ 1,520	\$ 342
Operating expenses:		
Research and development	8,268	9,331
General and administrative	6,371	4,138
Change in fair value of contingent consideration	224	
Loss from operations	(13,343)	(13,127)
Interest income (expense)	22	(519)
Other income, net	101	671
Net loss before income tax benefit	(13,220)	(12,975)
Income tax benefit	810	
Net loss	(12,410)	(12,975)
Net loss non-controlling interest	(568)	(401)
Net loss attributable to Heat Biologics, Inc.	\$ (11,842)	\$ (12,574)
Net loss per share attributable to Heat Biologics, Inc. - basic and diluted	\$ (3.08)	\$ (7.15)
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	3,845,342	1,758,621
	December 31, 2017	
	Actual	Pro Forma As Adjusted(1)
Balance Sheet Data: (in thousands)		
Cash and cash equivalents	\$ 9,763	\$ 29,643
Goodwill and In-process R&D	8,055	8,055

Other assets		2,371		2,371
Total Assets	\$	20,189	\$	40,069
Liabilities and Stockholders' Equity				
Accounts payable and other liabilities	\$	10,497	\$	10,497
Contingent consideration		2,609		2,609
Deferred tax liability		1,302		1,302
Total Liabilities		14,408		14,408
Common stock		1		4
Additional paid-in-capital		76,382		96,259
Accumulated deficit		(68,846)		(68,846)
Accumulated other comprehensive loss		(166)		(166)
Non-Controlling Interest		(1,590)		(1,590)
Total Liabilities and Stockholders' Equity	\$	20,189	\$	40,069

(1)

On a pro forma as adjusted basis to give effect to the issuance of 1,403,367 shares of common stock for which we received gross proceeds of \$3,571,081 from January 1, 2018 through and immediately prior to the date of this prospectus and to give effect to the sale by us of 3,000,000 shares of common stock in this offering at the public offering price of \$1.44 per share, the sale of 9,500,000 pre-funded warrants at the public offering price of \$1.43 per share and 6,250,000 common warrants at the public offering price of \$0.01 per common warrant, after deducting the estimated underwriting discounts and commissions and estimated offering expenses, and excluding the proceeds, if any, from the exercise of common warrants issued in this offering.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained or incorporated by reference in this prospectus, including our consolidated financial statements and the related notes, before making a decision to invest in our securities. You should also consider the risks, uncertainties and assumptions discussed under Item 1A, Risk Factors, in Part I of our Annual Report on Form 10-K for the year ended December 31, 2017 and Item 1A, Risk Factors, and any updates or other risks contained in other filings that we may make with the SEC after the date of this prospectus, all of which are incorporated herein by reference, and may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future and any additional prospectus supplement. If any of these risks actually occur, our business, results of operations and financial condition could suffer. In that case, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to this Offering

You will experience immediate and substantial dilution in the book value per share of the common stock and pre-funded warrants you purchase.

The public offering price per share of our common stock and each pre-funded warrant will be substantially higher than the net tangible book value per share of our common stock immediately prior to the offering. After giving effect to the sale of 3,000,000 shares of our common stock, at a public offering price of \$1.44 per share and the sale and exercise of pre-funded warrants to purchase shares of our common stock at an offering price of \$1.43 per pre-funded warrant (which is \$0.01 less than the public offering price per share of common stock) and after deducting the estimated underwriting discount and estimated offering expenses payable by us, purchasers of our common stock or pre-funded warrants in this offering will incur immediate dilution of \$0.47 per share in the net tangible book value of the common stock they acquire. For a further description of the dilution that investors in this offering will experience, see Dilution.

In addition, to the extent that outstanding stock options or warrants (including the exercise of any pre-funded warrants or common warrants) have been or may be exercised or other shares issued, you may experience further dilution.

Our management will have broad discretion over the use of proceeds from this offering and may not use the proceeds effectively.

Our management will have broad discretion over the use of proceeds from this offering. The net proceeds from this offering will be used to fund our and our subsidiaries' preclinical and clinical programs and for working capital and general corporate purposes, including, to acquire, license or invest in complementary businesses, technologies, product candidates or other intellectual property. Our management will have considerable discretion in the application of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not improve our operating results or enhance the value of our common stock.

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

Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and initiate and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. There are no other commitments by any person for future financing. Our securities may be offered to other investors at a price lower than the price per share offered to current stockholders, or upon terms which 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.

The pre-funded warrants and common warrants are speculative in nature.

Neither the pre-funded warrants nor the common warrants offered hereby confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the pre-funded warrants may exercise their right to acquire the common stock and pay an exercise price of \$0.01 per share of common stock and holders of the common warrants may exercise their right to acquire the common stock and pay an exercise price of 110% of the public offering price of the common stock. Moreover, following this offering, the market value of the pre-funded warrants and common warrants is uncertain and there can be no assurance that the market value of the pre-funded warrants or the common warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the pre-funded warrants or common warrants, and consequently, whether it will ever be profitable for holders of the pre-funded warrants to exercise the pre-funded warrants or the holders of the common warrants to exercise the common warrants.

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

Until you acquire shares of our common stock upon exercise of your pre-funded warrants or common warrants, you will have no rights with respect to shares of our common stock issuable upon exercise of your pre-funded warrant or common warrant, as applicable. Upon exercise of your pre-funded warrants or common warrant, you will be entitled to exercise the rights of a common stockholder as to the security exercised only as to matters for which the record date occurs after the exercise date.

There is no established market for the pre-funded warrants or common warrants to purchase shares of our common stock being offered in this offering.

There is no established trading market for the pre-funded warrants or common warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the pre-funded warrants or common warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the pre-funded warrants and common warrants will be limited.

Provisions of the pre-funded warrants offered by this prospectus could discourage an acquisition of us by a third party.

In addition to the discussion of the provisions of our third amended and restated certificate of incorporation, as amended, our bylaws and our stockholder rights plan, certain provisions of the pre-funded warrants and common warrants offered by this prospectus could make it more difficult or expensive for a third party to acquire us. The pre-funded warrants and common warrants prohibit us from engaging in certain transactions constituting fundamental transactions unless, among other things, the surviving entity assumes our obligations under the pre-funded warrants and common warrants. These and other provisions of the pre-funded warrants and common warrants offered by this prospectus could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

The exercise price of the pre-funded warrants and common warrants offered by this prospectus will not be adjusted for certain dilutive events.

The exercise price of the pre-funded warrants and common warrants offered by this prospectus is subject to adjustment for certain events, including, but not limited to, certain issuances of capital stock, options, convertible securities and other securities. However, the exercise prices will not be adjusted for dilutive issuances of securities considered excluded securities and there may be transactions or occurrences that may adversely affect the market price of our common stock or the market value of such pre-funded warrants and common warrants without resulting in an adjustment of the exercise prices of such pre-funded warrants or common warrants.

Risks Relating to our Company

We have had limited operations to date.

We are a clinical stage company and have had limited operations to date as has our subsidiary, Pelican. We have yet to demonstrate our ability to overcome the risks frequently encountered in our industry and are still subject to many of the risks common to such enterprises, including our ability to implement our business plan, market acceptance of our proposed business and products, under-capitalization, cash shortages, limitations with respect to personnel, financing and other resources, competition from better funded and experienced companies, and uncertainty of our ability to generate revenues. There is no assurance that our activities will be successful or will result in any revenues or profit, and the likelihood of our success must be considered in light of the stage of our development. Even if we generate revenue, which is not anticipated for several years, if at all, there can be no assurance that we will be profitable. In addition, no assurance can be given that we will be able to consummate our business strategy and plans, or that financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early stage company. Our revenue and income potential is unproven and our business model is continually evolving. We are subject to the risks inherent to the operation of a new business enterprise, and cannot assure you that we will be able to successfully address these risks.

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

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

.

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 significant experience in conducting cancer trials, to date, we have not successfully completed any late stage clinical trials and we have limited experience conducting and enrolling patients in clinical trials. Until recently, our operations, including the operations of Pelican, have been limited primarily to organizing and staffing, acquiring, developing and securing our proprietary technology and undertaking preclinical trials and preparing for our early clinical and preclinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

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

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

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

For the years ended December 31, 2017 and 2016, we incurred a net loss of \$12.4 million and \$13.0 million, respectively. We have an accumulated deficit of \$68.8 million through December 31, 2017. Pelican has also incurred net losses, which are included starting from the date of the acquisition of Pelican, in the net loss of \$12.4 million year ended December 31, 2017 and, resulted in a larger net loss. We expect to continue to incur operating losses until such time, if ever, as we are able to achieve sufficient levels of revenue from operations. Our ability to achieve profitability will depend on us obtaining regulatory approval for our product candidates and market acceptance of our product offerings and our capacity to develop, introduce and sell our products to our targeted markets. There can be no assurance that any of our product candidates will be approved for commercial sale, or even if our product candidates are approved for commercial sale that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

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

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

.
seek regulatory approvals for product candidates;

.
implement additional internal systems and infrastructure; and

.
hire additional personnel.

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

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

During the year ended December 31, 2017, our operating activities used net cash of approximately \$6.3 million and as of December 31, 2017, our cash and cash equivalents were approximately \$9.8 million. During the year ended December 31, 2016, our operating activities used net cash of approximately \$13.5 million and as of December 31, 2016 our cash and cash equivalents were approximately \$7.8 million. We have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, 2017, our accumulated deficit totaled approximately \$68.8 million and as of December 31, 2016, our accumulated deficit totaled approximately \$57.0 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. We do not expect to derive revenue from any significant source in the near future until we or our potential partners successfully commercialize our products. Despite cost-saving measures that we implemented, we expect our expenses to increase if and when we initiate and conduct Phase 3 and other clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and

other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future, we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees and grants.

We expect that our current cash and cash equivalents will allow us to continue the enrollment of additional patients in the Phase 2 clinical trial for HS-110; however, if the trial design or size were to change, we may need to raise money earlier than anticipated.

In addition to the proceeds received in this offering, we will need to raise additional capital to fund our future operations and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. To meet our financing needs, we are considering multiple alternatives, including, but not limited to, current and additional equity financings, which we expect will include sales of common stock through at the market issuances, debt financings and/or funding from partnerships or collaborations. Our ability to raise capital through the sale of securities may be limited by the various rules of the SEC and the NASDAQ Capital Market that place limits on the number and dollar amount of securities that we may sell. There can be no assurance that we will be able to meet the requirements for use of at-market-issuance agreements, especially in light of the fact that we are subject to the smaller reporting company requirements, or to complete any such transactions on acceptable terms or otherwise. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities, or continue to maintain our listing on the NASDAQ Capital Market. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

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

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

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

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. During the second quarter of 2017, we identified a material weakness in our controls over financial reporting related to the purchase price accounting for the acquisition that occurred during the quarter. Specifically, we did not design and maintain effective controls related to the acquisition for the purchase price of the acquired assets and liabilities of Pelican. Although the control deficiencies were remediated by the end of the fiscal year there can be no assurance that the internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

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

Our main focus and the investment of a significant portion of our efforts and financial resources has been in the development of our product candidate, HS-110, for which we are currently actively conducting a Phase 2 clinical trial. HS-110 is in clinical stage development. Our other product candidates are all at a pre-clinical stage. We expect that at least one Phase 3 clinical trial of HS-110 will be required to gain approval of the FDA. Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval, and commercialize our product candidates, which may never occur. Before commercializing this product candidate, we will require additional clinical trials and regulatory approvals for which there can be no guarantee that we will be successful. We currently generate no revenues from any of our product candidates, and we may never be able to develop or commercialize a marketable drug.

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

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

Risks Relating to our Business

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

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates or any product candidates we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a biologics license application (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 is our only current product candidate in clinical trials and our other product candidates are all in the preclinical stage of development. Although we have commenced a Phase 2 clinical trial for HS-110, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The results reported for our initial 26 patients in our Phase 2 clinical trial for HS-110 may not be replicated with other patients or other clinical trials. For example, the Phase 1 HS-410 clinical trial, as well as the interim data from the Phase 2 HS-410 clinical study, showed evidence of an immune response in NMIBC patients exposed to HS-410, however, the topline data from the Phase 2 clinical trial reported that there was no statistically significant difference in the primary endpoint between the vaccine and placebo arms of the trial. The Phase 2 clinical trial of HS-410 used doses and dosing regimens which had not previously been tested, and combinations with other immunotherapy agents. In addition, immune response is not an acceptable regulatory endpoint for approval, and the HS-410 Phase 1 trial involved a small sample size and was not randomized or blinded. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

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

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

·
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 institutional review board (IRBs) to oversee trials or in obtaining and maintaining IRB approval of studies;

.

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

.

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

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

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

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

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

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

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

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

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

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

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

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

We have developed certain experience in the formulation, development and/or manufacturing of biologics but do not intend to establish our own manufacturing facilities. To date, the selection and initial replication of our biological cell lines used in our trials has been performed by individuals working at third party laboratories over which we have little process or quality control and therefore the process and replication could be subject to human error. We lack the resources and expertise to formulate or manufacture our own product candidates. The investigational products for our clinical trials are manufactured by our contractors under current good manufacturing practices, (cGMPs) and we have entered into agreements with commercial-scale manufacturers for the production and supply of investigational product for additional Phase 2 and Phase 3 clinical trials as well as commercialization. Our agreement with the manufacturer of our HS-110 product expires in October 2019 and we have no assurance that we can extend the current agreement or renegotiate our agreement on favorable terms if at all. Manufacturing considerations which may include, lead time and capacity considerations of our third- party manufacturers to provide clinical supply of our product candidates, could delay our clinical trials. We must also develop and validate a potency assay prior to submission of a license application. Such assays have traditionally proven difficult to develop for cell-based products and must be established prior to initiating any Phase 3 clinical trials. If any of our current product candidates, or any product candidates we may develop or acquire in the future, receive FDA approval, we will rely on one or more third-party contractors for manufacturing. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

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

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

.

If we change the manufacturer of a product subsequent to the approval of the product, we will need to obtain approval from the FDA of the change in manufacturer. Any such approval would likely require significant testing and expense, and the new manufacturer may be subject to a cGMP inspection prior to approval.

.

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

.

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

.

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

.

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

.

Our contract manufacturers have in the past and may in the future encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. Our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to assess compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or

prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we or our contract manufacturers are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or could also result in higher costs or deprive us of potential product revenues.

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

For our product candidates we currently rely on third-party manufacturers to purchase from their third-party vendors the materials necessary to produce our product candidates and manufacture our product candidates for our clinical studies. If any of our third-party manufacturers were to experience any prolonged disruption for our manufacturing we could be forced to seek additional third-party manufacturing contracts, thereby increasing our development costs and negatively impacting our timeliness and any commercialization costs.

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

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

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

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

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

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

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

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products, if approved. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed

products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to successfully market and sell our products in the United States or overseas on our own.

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

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

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

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

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

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

.

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

.

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

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

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

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

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

The market for our product candidates is characterized by intense competition and rapid technological advances. If any of our product candidates receives FDA approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide

greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

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

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

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

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

condition.

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

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

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

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

- .
- 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 ending December 31, 2018, 2019, 2020, 2021, and 2022, our minimum annual payment obligations under our licensing agreements, (including the licenses that Pelican has entered into), required to be paid by us with the passage of time, are \$64,000, \$74,000, \$103,000, \$228,000 and \$784,000, respectively. No assurance can be given that we will generate sufficient revenue or raise additional financing to make these minimum royalty payments. The license agreements also provide for certain developmental milestones, including future payments to Pelican based on the achievement of certain milestones. No assurance can be given that we will meet all of the required developmental milestones. Any failure to make the payments or reach the milestones required by the license agreements would permit the licensor to terminate the license. If we were to lose or otherwise be unable to maintain these licenses, it would halt our ability to market our products and technology, which would have an immediate material adverse effect on our business, operating results and financial condition.

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

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

.

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, uncertainty remains regarding proposed significant reforms to the U.S. health care system.

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

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities; augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

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

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

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

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

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

We will need to hire additional qualified personnel with expertise in preclinical and clinical research, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. In particular, over the next 12 months, we expect to hire additional new employees both in North Carolina and for Pelican in Texas. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

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

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

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

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

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

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

.

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

.

difficulties in managing foreign operations;

.

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

.

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

.

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

.

reduced protection for intellectual property rights;

.

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

.

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

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

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

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

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

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

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

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

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

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

Risk Factors Relating to the Pelican Acquisition (the Acquisition)

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

Neither we nor Pelican are expected to derive revenue from any source in the near future until we, they or other potential partners successfully commercialize products. The CPRIT Grant requires that Pelican provide matching funds for one half of the award amount in order for Pelican to receive the grant funding. In order to receive the full \$15.2 million award over three years, Pelican must raise matching funds in the aggregate amount of approximately \$7.6 million. Pelican has received from us matching funds in the amount of approximately \$1.2 million as of December 31, 2017. CPRIT has made available to Pelican the grant award in the amounts of approximately \$1.8 million for the first contract fiscal year (June 2016 - May 2017) and approximately \$6.5 million for the second contract fiscal year (June 2017 - May 2018). Pelican must provide matching funds of approximately \$3.2 million for the second fiscal year grant. For the third fiscal year (June 2018 through May 2019) of the award Pelican must provide matching funds of approximately \$3.5 million in order for CPRIT to provide approximately \$7.0 million of grant funding. In addition, we have agreed to provide Pelican approximately \$0.3 million to pay Pelican's legal fees and expenses incurred in connection with the Acquisition. Our financial statements have been prepared under the assumption that we will continue as a going concern; however, we have incurred significant losses from operations to date and we expect our expenses to increase in connection with our ongoing activities, and the addition of Pelican's activities. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our or Pelican's technologies or tests or grant licenses on terms that are not favorable to us. If we do not succeed in raising additional funds on acceptable terms or at all, we may be unable to complete planned preclinical and clinical trials, access the CPRIT award or obtain approval of our product candidates from the FDA and other regulatory authorities.

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

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

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

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

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

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

.

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

.

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

.

minimizing potential adverse effects on existing business relationships;

.

successfully developing the new products and services; and

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

Risks Related to Our Common Stock

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

Our shares of common stock are currently listed on the NASDAQ Capital Market. If we fail to satisfy the continued listing requirements of the NASDAQ Capital Market, such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder's equity requirement, the NASDAQ Capital Market may take steps to de-list our common stock. Any de-listing would likely have a negative effect on the price of our common stock and would impair stockholders' ability to sell or purchase their common stock when they wish to do so. On March 15, 2017, we received written notice from the Listing Qualifications Department of NASDAQ Stock Market LLC (NASDAQ) notifying us that for the preceding 30 consecutive business days (January 31, 2017 through March 14, 2017), our common stock did not maintain a minimum closing bid price of \$1.00 per share (Minimum Bid Price Requirement) as required by NASDAQ Listing Rule 5550(a)(2). On September 12, 2017, we received written notice from NASDAQ that we had been granted an additional 180-day extension, or until March 12, 2018, to regain compliance with the Minimum Bid Price Requirement. On January 19, 2018, we effected a one-for-ten reverse split of our common stock in order to regain compliance with the NASDAQ Minimum Bid Price Requirement. On February 5, 2018, we were notified by NASDAQ that we had regained compliance with the Minimum Bid Price Requirement and that the matter was closed. No assurance can be given that we will continue to remain compliant with the NASDAQ Minimum Bid Price Requirement or NASDAQ's other continued listing requirements.

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

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

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

Sales of additional shares of common stock, including by us or our directors and officers following expiration or early release of the lock-up periods, could cause the price of our common stock to decline.

Sales of substantial amounts of our common stock in the public market, or the availability of such shares for sale, by us or by others, including the issuance of shares of common stock upon the exercise of outstanding options and warrants, could adversely affect the price of our common stock. In connection with this offering, we and our directors and officers have entered into lock-up agreements for a period of 90 days following this offering. We and our directors and officers may be released from the lock-up prior to its expiration period at the sole discretion of the representative of the underwriters. See "Underwriting." Upon expiration or earlier release of the lock-up, we and our directors and officers may sell shares of our common stock into the market, which could adversely affect the market price of our common stock.

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

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

In addition, as of December 31, 2017, we had outstanding warrants exercisable for 1,738 shares of our common stock on post reverse stock split basis to third parties in connection with prior private placements of our equity securities and debt, warrants exercisable for 296,159 shares of our common stock on a post reverse stock split basis to third parties in connection with a public offering, and warrants exercisable for 12,500 shares of our common stock on a post reverse stock split basis to underwriters in connection with our initial public offering. To the extent that outstanding stock options and warrants are exercised, or additional securities are issued, dilution to the interests of our stockholders may occur. Moreover, the terms upon which we will be able to obtain additional equity capital may be adversely affected since the holders of the outstanding options can be expected to exercise them at a time when we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than those provided in such outstanding options.

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

Our third amended and restated certificate of incorporation, as amended, authorizes the issuance of 100,000,000 shares of our common stock and 10,000,000 shares of preferred stock. In certain circumstances, the common stock, as well as the awards available for issuance under our equity 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. In addition, the issuance of certain securities, including pursuant to the terms of our stockholder rights plan, may be used as an anti-takeover device without further action on the part of our stockholders, and may adversely affect the holders of the common stock.

In addition, the issuance of preferred stock may be used as an anti-takeover device, and may adversely affect the holders of the common stock. If our board of directors and stockholders approved the use of blank check preferred stock, our board of directors would be authorized to create and issue from time to time, without further stockholder approval, a certain number of shares of preferred stock, in one or more series and to establish the number of shares of any series of preferred stock and to fix the designations, powers, preferences and rights of the shares of each series and any qualifications, limitations or restrictions of the shares of each series. The authority to designate preferred stock may be used to issue series of preferred stock, or rights to acquire preferred stock, that could dilute the interest of, or impair the voting power of, holders of the common stock or could also be used as a method of determining, delaying or preventing a change of control.

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

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our board of directors. To date, we have paid no cash dividends on our shares of our preferred or common stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, to provide funds for

operations of our business. Therefore, any return investors in our preferred or common stock may have will be in the form of appreciation, if any, in the market value of their shares of common stock.

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

We are an emerging growth company, as defined in the JOBS Act enacted in April 2012, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any new requirements adopted by the Public Company Accounting Oversight Board, or the PCAOB, requiring a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer, not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the SEC determines otherwise, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could remain an emerging growth company until the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile. Further, as a result of these scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to stockholders of such companies.

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

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

On May 1, 2018, 2018, we had 5,663,919 shares of our common stock outstanding, all of which are currently eligible for sale in the public market, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 promulgated under the Securities Act. It is conceivable that stockholders may wish to sell some or all of their shares. If our stockholders sell substantial amounts of our common stock in the public market at the same time, the market price of our common stock could decrease significantly due to an imbalance in the supply and demand of our common stock. Even if they do not actually sell the stock, the perception in the public market that our stockholders might sell significant shares of our common stock could also depress the market price of our common stock.

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

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

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

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

Our stock price and the trading volume of our stock continues to be very volatile. Our closing stock price has recently increased 95% from a closing price of \$2.14 on April 30, 2018 to \$4.17 on May 1, 2018 and \$2.48 on May 2, 2018 and was \$1.11 on April 20, 2018. In addition, investors may find it difficult to obtain accurate stock price quotations

and holders of our stock may be unable to resell their stock at desirable prices. Sales of substantial amounts of our common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short period of time. As a result, our stockholders could suffer losses or be unable to liquidate holdings.

Certain provisions of the General Corporation Law of the State of Delaware, 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.

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

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

Our previously issued warrants may not have any value.

Our previously issued warrants to purchase shares of our common stock may not have any value. For example, we previously issued warrants in a public offering that have an exercise price of \$10.00 per share (post-reverse stock split) and issued warrants to underwriters in connection with our initial public offering that have an exercise price of \$125.00 per share (post-reverse stock split). In the event that our common stock price does not exceed the exercise price of our previously issued warrants during the period when the pre-funded warrants are exercisable, the pre-funded 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 pre-funded warrants will be limited.

The shares of common stock offered under the H.C. Wainwright Sales Agreement may be sold in at the market offerings, and investors who buy shares at different times will likely pay different prices.

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

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

Securities research analysts, including those affiliated with our underwriters from prior offerings, establish and publish their own periodic projections for our business. These projections may vary widely from one another and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match securities research analysts' projections. Similarly, if one or more of the analysts who writes reports on us downgrades

our stock or publishes inaccurate or unfavorable research about our business or if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, our stock price or trading volume could decline. While we expect securities research analyst coverage to continue going forward, if no securities or industry analysts begin to cover us, the trading price for our stock and the trading volume could be adversely affected.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements, including statements regarding the progress and timing of our product development, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, our expected future revenues, operations and expenditures and projected cash needs. The forward-looking statements are contained principally in the sections entitled Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business. These statements relate to future events of our financial performance and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. Those risks and uncertainties include, among others:

- .
our ability to implement our business plan;
- .
our ability to raise additional capital to meet our liquidity needs;
- .
our ability to generate sufficient proceeds from this offering;
- .
our ability to generate product revenues;
- .
our ability to achieve profitability;
- .
our ability to satisfy U.S. (including the FDA), and international regulatory requirements;
- .
our ability to obtain market acceptance of our technology and products;
- .

our ability to compete in the market;

.

our ability to advance our clinical trials;

.

our ability to fund, design and implement clinical trials;

.

our ability to demonstrate that our product candidates are safe for human use and effective for indicated uses;

.

our ability to gain acceptance of physicians and patients for use of our products;

.

our dependency on third-party researchers and manufacturers and licensors;

.

our ability to effectively implement cost-cutting measures;

.

our ability to establish and maintain strategic partnerships, including for the distribution of products;

.

our ability to attract and retain sufficient, qualified personnel;

.

our ability to obtain or maintain patents or other appropriate protection for the intellectual property;

.

our dependency on the intellectual property licensed to us or possessed by third parties;

.

our ability to adequately support future growth;

.

our ability to maintain our NASDAQ listing;

.

Pelican, ability to operate successfully and our ability to integrate our operations with those of Pelican; and

potential product liability or intellectual property infringement claims.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expects, plans, anticipates, estimates, projects, predicts, potential, or the negative of those terms, and similar expressions and comparative terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. You should read this prospectus, the documents incorporated by reference in this prospectus, the documents referenced in this prospectus and the documents filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

USE OF PROCEEDS

We estimate that the net proceeds of this offering will be approximately \$16.2 million, in connection with the sale of 3,000,000 shares of our common stock, 6,250,000 common warrants and 9,500,000 pre-funded warrants or approximately \$18.7 million if the underwriters exercise in full their option to purchase all additional 1,875,000 shares of common stock and 937,500 common warrants, at the public offering price of \$1.44 per share for the common stock, \$1.43 per share for the pre-funded warrants and \$0.01 for the common warrants, after deducting the estimated underwriting discount and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the pre-funded warrants or the common warrants. The public offering price per common share or pre-funded warrant was determined between us, the underwriter and investors based on market conditions at the time of pricing. We will only receive additional proceeds from the exercise of the pre-funded warrants issuable in connection with this offering if such warrants are exercised at their exercise price of \$0.01 and the holders of such warrants pay the exercise price in cash upon such exercise and do not utilize the cashless exercise provision of the pre-funded warrants. Such proceeds with respect to the pre-funded warrants will not exceed \$95,000, assuming no exercise of the underwriters to purchase additional shares of common stock. We will only receive additional proceeds from the exercise of the common warrants issuable in connection with this offering if such warrants are exercised at their exercise price of \$1.584 and the holders of such warrants pay the exercise price in cash upon such exercise and do not utilize the cashless exercise provision of the common warrants.

Except where indicated, the foregoing discussion assumes no exercise of the underwriters' option to purchase up to 1,875,000 additional shares of common stock and/or the accompanying common warrants to purchase up to 937,500 shares of common stock.

We intend to use the net proceeds, if any, from the sales of securities offered by this prospectus to fund our and our subsidiaries' preclinical and clinical programs and for working capital and general corporate purposes, including, to acquire, license or invest in complementary businesses, technologies, product candidates or other intellectual property. We have broad discretion in determining how the proceeds of this offering will be used, and our discretion is not limited by the aforementioned possible uses. Our board of directors believes the flexibility in application of the net proceeds is prudent.

The amounts and timing of our actual expenditures will depend on numerous factors, including our development and commercialization efforts, as well as the amount of cash used in our operations. We therefore cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities.

CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2017:

on an actual basis, adjusted to reflect the reverse stock split of one-for-ten effective January 19, 2018;

on a pro forma basis to give effect to the issuance of 1,403,367 shares of common stock for which we received gross proceeds of \$3,571,081 from January 1, 2018 through and immediately prior to the date of this prospectus; and

on a pro forma as adjusted basis to give effect to (i) the issuance of 1,403,367 shares of common stock for which we received gross proceeds of \$3,571,081 from January 1, 2018 through and immediately prior to the date of this prospectus and (ii) the sale of 3,000,000 shares of common stock in this offering at the public offering price of \$1.44 per share, common warrants to purchase 6,250,000 shares of common stock and 9,500,000 pre-funded warrants at the public offering price of \$1.43 per share and assuming exercise of the pre-funded warrants, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The pro forma as adjusted basis excludes the proceeds, if any, from the exercise of any common warrants issued in this offering.

This capitalization table should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our historical financial statements and notes to those financial statements that are incorporated by reference in this prospectus.

	As of December 31, 2017		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	\$ 9,763,067	\$ 13,334,148	\$ 29,643,298
Common stock, \$0.0002 par value; 100,000,000 shares authorized, 4,200,310 shares issued and outstanding, actual;	840	1,121	3,621

Edgar Filing: HEAT BIOLOGICS, INC. - Form 424B4

Preferred Stock, \$0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding			
Additional paid-in capital	76,382,262	79,953,062	96,259,712
Accumulated deficit	(68,846,326)	(68,846,326)	(68,846,326)
Accumulated other Comprehensive Loss	(166,025)	(166,025)	(166,025)
Total Stockholders' Equity Heat Biologics, Inc.	7,370,751	10,941,832	27,250,982
Non-Controlling Interest	(1,589,842)	(1,589,842)	(1,589,842)
Total stockholders' equity	5,780,909	9,351,990	25,661,140
Total capitalization	\$ 20,189,476	\$ 23,760,557	\$ 40,069,707

Unless we indicate otherwise, all information in this Capitalization section:

.

reflects a one-for-ten reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on January 19, 2018 and the corresponding adjustment of all common stock prices per share and stock option and warrant exercise prices per share and conversion ratios;

.

assumes no exercise by the underwriters of their over-allotment option;

.

excludes 266,810 shares of our common stock issuable upon exercise of outstanding options under our equity incentive plans at a weighted-average exercise price of \$19.57 per share;

.

excludes 310,397 shares of our common stock reserved for issuance upon the exercise of outstanding warrants with a weighted-average exercise price of \$14.60 per share; and

.

excludes 553,196 shares of our common stock that are reserved for equity awards that may be granted under our equity incentive plans.

DILUTION

If you purchase shares of our securities in this offering, you will experience dilution to the extent of the difference between the public offering price per share and pre-funded warrant in this offering and our as adjusted net tangible book value per share immediately after this offering. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the number of outstanding shares of our common stock. As of December 31, 2017, our net tangible book value was approximately \$(2,274,429), or approximately \$(0.53) per share.

Our pro forma net tangible book value as of December 31, 2017 was \$1,296,652 or \$0.23 per share of common stock, based upon 5,663,919 shares outstanding, after giving effect to issuances of 1,403,367 shares of common stock for which we received gross proceeds of \$3,571,081 from January 1, 2018 through and immediately prior to the date of this prospectus. After giving effect to the sale by us of 3,000,000 shares of our common stock in this offering at a public offering price of \$1.44 per share, the accompanying common warrants at a purchase price of \$0.01 per common warrant and 9,500,000 pre-funded warrants at the public offering price of \$1.43 per share in this offering assuming the exercise of pre-funded warrants, and excluding the proceeds, if any, from the exercise of the common warrants and after deducting the estimated underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2017 would have been approximately \$17.6 million, or approximately \$0.97 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$0.74 per share to existing stockholders and an immediate dilution of \$0.47 per share to new investors purchasing securities in this offering. The following table illustrates this per share dilution:

Public offering price per share of common stock	\$	1.44
Pro forma net tangible book value per share as of December 31, 2017	\$	0.23
Increase in pro forma net tangible book value per share after this offering	\$	0.74
Pro forma as adjusted net tangible book value per share after giving effect to this offering		0.97
Dilution per share to new investors	\$	0.47

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to \$1.00 per share, representing an immediate increase to existing stockholders of \$0.77 per share and an immediate dilution of \$0.44 per share to new investors.

The foregoing discussion and table do not take into account further dilution to new investors that could occur upon the exercise of outstanding options or warrants, including the pre-funded warrants having a per share exercise price less than the per share offering price to the public in this offering, and the common warrants offered hereby. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we

have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**Market Information**

Our common stock has traded on the NASDAQ Capital Market under the symbol **HTBX** since July 29, 2013. Prior to that time, there was no public market for our common stock. The following table states the range of the high and low sales prices of our common stock for the year ended December 31, 2016, and the year ended December 31, 2017 and the first fiscal quarter of 2018 (as adjusted to reflect the one-for-ten reverse stock split effective January 19, 2018). These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NASDAQ on May 2, 2018 was \$2.48 per share. As of May 2, 2018, there were approximately 70 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name.

On January 19, 2018, we announced a reverse stock split of our shares of common stock at a ratio of one-for-ten. The reverse stock split took effect at 11 p.m. ET on January 19, 2018, and our common stock began to trade on a post-split basis at the market open on January 22, 2018. During our annual stockholders meeting held June 29, 2017, shareholders approved our company's reverse stock split, and granted the board of directors the authority to implement and determine the exact split ratio. When the reverse stock split became effective, every 10 shares of our issued and outstanding common stock were combined into one share of common stock. Effecting the reverse stock split reduced the number of issued and outstanding common stock from approximately 42 million shares to approximately 4.2 million. It also subsequently adjusted outstanding options issued under our equity incentive plan and outstanding warrants to purchase common stock.

	High	Low
YEAR ENDED DECEMBER 31, 2016		
First Quarter	\$ 43.20	\$ 6.80
Second Quarter	\$ 8.00	\$ 4.59
Third Quarter	\$ 18.10	\$ 6.61
Fourth Quarter	\$ 32.30	\$ 6.96
YEAR ENDED DECEMBER 31, 2017		
First Quarter	\$ 10.80	\$ 8.05
Second Quarter	\$ 8.68	\$ 5.62
Third Quarter	\$ 6.80	\$ 4.75
Fourth Quarter	\$ 7.59	\$ 3.50
YEAR ENDED DECEMBER 31, 2018		
First Quarter	\$ 4.29	\$ 1.63
Second quarter through May 2, 2018	\$ 4.30	\$ 1.09

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We expect to retain all available funds and future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends, if any, on our common stock will be at the discretion of our board of directors and will depend on, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

DESCRIPTION OF OUR SECURITIES

General

The following is a summary of the rights of our common stock and outstanding warrants and related provisions of our third amended and restated certificate of incorporation, as amended (the certificate of incorporation), amended and restated bylaws (bylaws) and warrants. For more detailed information, please see our certificate of incorporation and bylaws.

We are authorized to issue 100,000,000 shares of common stock, par value \$0.0002 per share, of which 5,663,919 shares are outstanding as of May 1, 2018 and 10,000,000 shares of preferred stock, par value \$0.0001 per share, of which 112,500 shares are designated Series 1 Preferred Stock, 2,000,000 shares are designated Series A Preferred Stock, 4,100,000 are designated as Series B-1 Preferred Stock and 2,000,000 are designated Series B-2 Preferred Stock. There are currently no shares of Preferred Stock outstanding.

All share and per share numbers in this prospectus have been adjusted to reflect the one-for-ten reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on January 19, 2018.

Common Stock

The holders of our common stock are entitled to one vote per share on all matters to be voted on by the shareholders. Subject to preferences that may be applicable to any outstanding shares of Preferred Stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefore. If we liquidate, dissolve or wind up, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of Preferred Stock. Holders of common stock have no preemptive, conversion or subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are, and all shares of common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable. Except as otherwise required by Delaware law, all stockholder action, other than the election of directors, is taken by the vote of a majority of the outstanding shares of common stock voting as a single class present at a meeting of stockholders at which a quorum consisting of a majority of the outstanding shares of common stock is present in person or proxy. The election of directors by our stockholders, is determined by a plurality of the votes cast by the stockholders entitled to vote at any meeting held for such purposes at which a quorum consisting of a majority of the outstanding shares of common stock is present in person or proxy.

Reverse Stock Splits

We effected a 1-for-2.3 reverse stock split on May 29, 2013 and a 1-for-10 reverse stock split on January 19, 2018. The one-for-ten reverse stock split was implemented in order to regain compliance with the Nasdaq Capital Market minimum stock price continued listing requirements.

Preferred Stock

We are authorized to issue 10,000,000 shares of Preferred Stock, par value \$.0001 per share, of which 112,500 shares have been designated Series 1 Preferred Stock, 2,000,000 shares have been designated Series A Preferred Stock, 4,100,000 have been designated as Series B-1 Preferred Stock and 2,000,000 have been designated Series B-2 Preferred Stock. None of such shares of Preferred Stock are outstanding. Any authorized and undesignated shares of preferred stock may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by our board of directors and approved by our stockholders.

Outstanding Common Stock Warrants

On March 10, 2011, we issued warrants to purchase 3,261 shares of common stock to non-employee placement agents in consideration for a private equity placement transaction. The warrants were issued with an exercise price of \$4.80 per share and expire 10 years from the issuance date. In February 2014, warrants to purchase 1,523 shares of common stock were exercised in cashless transactions that resulted in the issuance of 1,432 shares of our common stock, which resulted in warrants to purchase 1,738 shares of common stock outstanding as of December 31, 2017.

In connection with our initial public offering, we issued warrants to the underwriters for 12,500 shares of common stock issuable at \$125.00 per share upon exercise. The warrants have a five-year life and expire on July 23, 2018. In addition, the warrants provide for registration rights upon request, in certain cases. The holders of the warrants were granted demand registration rights for a period of five years from the effective date of the offering and piggyback registration rights for a period of seven years from the effective date of the offering. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

In connection with our March 2016 public offering, we issued warrants to purchase 682,500 shares of our common stock, at an exercise price of \$10.00 per share of which 296,159 are outstanding as of December 31, 2017. The warrants have a five-year life and expire after March 22, 2021.

Stock Incentive Plans

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

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. 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 the us one share of common stock at a price of \$14.00 per share of common stock (the Purchase Price), subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement, dated as of March 11, 2018, as the same may be 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, 2019, 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 third amended and restated certificate of incorporation, as amended, in our bylaws, our stockholder rights plan 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 our stockholder rights plan, 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 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.

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

Our common stock is currently listed on the NASDAQ Capital Market under the trading symbol **HTBX**.

Transfer Agent

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

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 3,000,000 shares of our common stock and common warrants to purchase 6,250,000 shares of common stock. We are also offering 9,500,000 pre-funded warrants to each purchaser whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering. Subject to limited exceptions, a holder of pre-funded warrants will not have the right to exercise any portion of its pre-funded warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each pre-funded warrant is being sold together with a common warrant with the same terms as the common warrant accompanying the common stock. Because a common warrant is being sold together in this offering with each share of common stock and, in the alternative, each pre-funded warrant to purchase one share of common stock, the number of common warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold.

Common Stock

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption *Description of Our Securities* in this prospectus.

Pre-Funded Warrants

The following summary of certain terms and provisions of pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Form. The pre-funded warrants will be issued as individual warrant agreements to the investors. The form of pre-funded warrant is filed as an exhibit to this registration statement.

Exercisability. The pre-funded warrants are exercisable at any time after their original issuance and may be exercised at any time until all of the pre-funded warrants are exercised in full. The pre-funded warrants will be exercisable, at

the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If at the time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares of common stock to the holder, then the pre-funded warrant may only be exercised through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre-funded warrant. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares.

Exercise Limitations. Under the pre-funded warrants, we may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99%/9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 4.99%/9.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the pre-funded warrants is \$0.01 per share of common stock. The exercise price of the pre-funded warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. We do not plan on applying to list the pre-funded warrants on The NASDAQ Capital Market, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the pre-funded warrants. In the event of a fundamental transaction, we are required to cause any successor entity to assume all of our obligations under the pre-funded warrants.

No Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the pre-funded warrant.

Common Warrants

The following summary of certain terms and provisions of the common warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant agent agreement, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of warrant agent agreement for a complete description of the terms and conditions of the common warrants.

Book-entry Form. Pursuant to a warrant agent agreement between us and Continental Stock Transfer & Trust Company, as warrant agent, the common warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

The common warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a common warrant will not be deemed a holder of our underlying common stock until the common warrant is exercised, except as set forth in the common warrant.

The common warrants will be issued separately from the common stock and pre-funded warrants, and may be transferred separately immediately thereafter. A common warrant to purchase 0.50 of a share of our common stock will be issued for every one share of common stock or pre-funded warrant purchased in this offering.

Exercisability. The common warrants are exercisable at any time after their original issuance and will expire on the fifth anniversary of the original issuance date, subject to our call option described below. The common warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If at the time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares of common stock to the holder, then the common warrant may only be exercised through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the common warrant. No fractional shares of common stock will be issued in connection with the exercise of a common warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares.

Exercise Limitations. Under the common warrants, we may not effect the exercise of any common warrant, and a holder will not be entitled to exercise any portion of any common warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99%/9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 4.99%/9.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days prior notice from the holder to us.

Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the common warrants is \$1.584. The exercise price of the common warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Call Option. If there is a registration statement that covers the resale of the shares underlying the common warrants or all of such shares may be sold pursuant to Rule 144 upon cashless exercise without restrictions, including volume restrictions, we have the option to call the exercise of any or all of the common warrants, from time to time by giving a call notice to the holder only after any 10-consecutive trading day period during which the daily VWAP of the common stock is not less than 300% of the exercise price for the common warrants in effect for such 10-consecutive trading day period. During the call period, the holder may exercise the common warrant and purchase the called common stock underlying the common warrant. If the holder fails to timely exercise the common warrant or a number of shares of common stock equal to number of called shares of common stock during the call period, our sole remedy will be to cancel an amount of called shares of common stock underlying the common warrant equal to such shortfall, with the common warrant no longer being exercisable with respect to such shares of common stock. The call period is a period of 30 trading days following the date on which the call notice is deemed given and effective.

Transferability. Subject to applicable laws, the common warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. We do not plan on applying to list the common warrants on The NASDAQ Capital Market, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, as described in the common warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the common warrants. In the event of a fundamental transaction, we are required to cause any successor entity to assume all of our obligations under the common warrants.

Right as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a common warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the common warrant.

MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK, PRE-FUNDED WARRANTS AND COMMON WARRANTS

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock and pre-funded warrants and common warrants (collectively, for purposes of this Section, the warrants) acquired in this offering. This discussion is based on the current provisions of the Internal Revenue Code of 1986, as amended (The Code), existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service (the IRS) with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, pre-funded warrants or common warrants, or that any such contrary position would not be sustained by a court. This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the alternative minimum tax and does not deal with state or local taxes, U.S. federal gift and estate tax laws, or any non-U.S. tax consequences that may be relevant to holders in light of their particular circumstances.

Special rules different from those described below may apply to certain holders that are subject to special treatment under the Code, such as:

- insurance companies, banks and other financial institutions;
- tax-exempt organizations (including private foundations) and tax-qualified retirement plans;
- foreign governments and international organizations;
- broker-dealers and traders in securities;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons that own, or are deemed to own, more than 5% of our capital stock;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- persons that hold our common stock, pre-funded warrants or common warrants as part of a straddle, hedge, conversion transaction, synthetic security or integrated investment or other risk reduction strategy;
- persons who do not hold our common stock or pre-funded warrants or common warrants as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); and
- partnerships and other pass-through entities, and investors in such pass-through entities (regardless of their places of organization or formation).

Such holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them.

PERSONS CONSIDERING THE PURCHASE OF OUR COMMON STOCK, PRE-FUNDED WARRANTS OR COMMON WARRANTS PURSUANT TO THIS OFFERING SHOULD CONSULT THEIR OWN TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME TAX CONSEQUENCES OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, PRE-FUNDED WARRANTS OR COMMON WARRANTS IN LIGHT OF THEIR PARTICULAR SITUATIONS AS WELL AS ANY CONSEQUENCES ARISING UNDER THE

LAWS OF ANY OTHER TAXING JURISDICTION, INCLUDING ANY STATE, LOCAL OR NON-U.S. TAX CONSEQUENCES OR ANY U.S. FEDERAL NON-INCOME TAX CONSEQUENCES, AND THE POSSIBLE APPLICATION OF TAX TREATIES.

For the purposes of this discussion, a **U.S. Holder** means a beneficial owner of our common stock, pre-funded warrants or common warrants that is for U.S. federal income tax purposes (a) an individual citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A **Non-U.S. Holder** is, for U.S. federal income tax purposes, a beneficial owner of common stock, pre-funded warrants or common warrants that is not a U.S. Holder or a partnership for U.S. federal income tax purposes.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, a pre-funded warrant should be treated as a share of our common for U.S. federal income tax purposes. Accordingly, upon exercise, the holding period of a pre-funded warrant will carry over to the share of common stock received. Similarly, the tax basis of the pre-funded warrant should carry over to the share of common stock received upon exercise increased by the exercise price of \$0.01.

Allocation of Purchase Price and Characterization of a Common Warrant

For U.S. federal income tax purposes, each holder must allocate the purchase price of the warrant based on its fair market value at the time of issuance. The price allocated to each common warrant generally will be the holder's tax basis in such common warrant.

Tax Considerations Applicable to U.S. Holders

Exercise and Expiration of Warrants

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant, except to the extent the U.S. Holder receives a cash payment for a such fractional share that would otherwise have been issuable upon exercise of the warrant, which will be treated as a sale subject to the rules described under *Gain on Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants* below. The U.S. Holder will take a tax basis in the shares acquired on the exercise of a warrant equal to the exercise price of the warrant. The U.S. Holder's holding period in the shares of our common stock acquired on exercise of the warrant will begin on the date of exercise of the warrant, and will not include any period for which the U.S. Holder held the warrant. The lapse or expiration of a warrant will be treated as if the U.S. Holder sold or exchanged the warrant and recognized a capital loss equal to the U.S. Holder's tax basis in the warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the warrants, or an adjustment to the exercise price of the warrants, may be treated as a constructive distribution to a U.S. Holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our earnings and profits or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants made pursuant to a *bona fide* reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the warrants generally should not be considered to result in a constructive distribution. Such constructive distribution would be treated as a dividend, return of capital or capital gain as described under the heading *Distributions* below. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property.

On April 12, 2016, the IRS issued proposed regulations addressing the amount and timing of deemed distributions, obligations of withholding agents and filing and notice obligations of issuers. If adopted as proposed, the regulations would generally provide that (i) the amount of a deemed distribution is the excess of the fair market value of a warrant immediately after the number-of-shares or exercise-price adjustment over the fair market value of the warrant without the adjustment, (ii) the deemed distribution occurs at the earlier of the date the adjustment occurs under the terms of the warrant and the date of the actual distribution of cash or property that results in the deemed distribution, and (iii) we are required to report the amount of any deemed distributions on our website or to the IRS and all holders of warrants (including holders of warrants that would otherwise be exempt from reporting). The final regulations will be effective for deemed distributions occurring on or after the date of adoption, but holders of warrants agents may rely on them prior to that date under certain circumstances.

Distributions

Distributions on our common stock, pre-funded warrants or common warrants made to a U.S. Holder will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Such dividends paid by us to an individual U.S. Holder generally will be qualified dividends taxed at a maximum 20% tax rate. Such dividends paid by us will be taxable to a corporate U.S. Holder at regular rates (of 21%), but should be eligible for the dividends-received deduction generally allowed to domestic corporations in respect of dividends received from other domestic corporations. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a U.S. Holder's adjusted tax basis in our common stock or pre-funded warrant, as applicable. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock or pre-funded warrant as described below under the section titled *Gain on Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants*.

Gain on Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants

Upon a sale or other taxable disposition of our common shares, pre-funded warrants or common warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the ordinary shares or warrants. U.S. Holders are taxed on short-term capital gain in the same manner as ordinary income, but non-corporate U.S. holders are taxed on long-term capital gain at a maximum tax rate of 20%. Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder's holding period for the common stock, pre-funded warrant or common warrants exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. Holders who recognize losses with respect to a disposition of our common stock, pre-funded warrants or common warrants should consult their own tax advisors regarding the tax treatment of such losses.

Unearned Income Medicare Tax

A 3.8% Medicare contribution tax will generally apply to all or some portion of the net investment income of a U.S. Holder that is an individual with adjusted gross income that exceeds a threshold amount (\$250,000 if married filing jointly or if considered a surviving spouse for federal income tax purposes, \$125,000 if married filing separately, and \$200,000 in other cases). This 3.8% tax will also apply to all or some portion of the undistributed net investment income of certain U.S. Holders that are estates and trusts. For these purposes, dividends and gains from the taxable dispositions of the ordinary shares and warrants will generally be taken into account in computing such a U.S. Holder's net investment income.

Tax Reporting

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on the common stock and pre-funded warrants and to the proceeds of a sale or other disposition of common stock and pre-funded warrants paid by us to a U.S. holder unless such U.S. holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. holder fails to provide the holder's taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption.

Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against the U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Tax Considerations Applicable To Non-U.S. Holders

Exercise and Expiration of Warrants

In general, a Non-U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant, except to the extent the Non-U.S. Holder receives a cash payment for a fractional share that would otherwise have been issuable upon exercise of the warrant, which will be treated as a sale subject to the rules described under *Gain on Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants* below. The Non-U.S. Holder will take a tax basis in the shares acquired on the exercise of a warrant equal to the exercise price of the warrant. The Non-U.S. Holder's holding period in the shares of our common stock acquired on exercise of the warrant will begin on the date of exercise of the warrant, and will not include any period for which the Non-U.S. Holder held the warrant.

The expiration of a warrant will be treated as if the Non-U.S. Holder sold or exchanged the warrant and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a warrant against the Non-U.S. Holder's U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is present 183 days or more in the taxable year of disposition and certain other conditions are met.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the warrants, or an adjustment to the exercise price of the warrants, may be treated as a constructive distribution to a Non-U.S. Holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such Non-U.S.

Holder's proportionate interest in our earnings and profits or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants made pursuant to a *bona fide* reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the warrants generally should not be considered to result in a constructive distribution. Such constructive distribution would be treated as a dividend, return of capital or capital gain as described under the heading "Distributions" below. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property.

On April 12, 2016, the IRS issued proposed regulations addressing the amount and timing of deemed distributions, obligations of withholding agents and filing and notice obligations of issuers. If adopted as proposed, the regulations would generally provide that (i) the amount of a deemed distribution is the excess of the fair market value of a warrant immediately after the number-of-shares or exercise-price adjustment over the fair market value of the warrant without the adjustment, (ii) the deemed distribution occurs at the earlier of the date the adjustment occurs under the terms of the warrant and the date of the actual distribution of cash or property that results in the deemed distribution, (iii) subject to certain limited exceptions, a withholding agent is required to impose any applicable withholding on deemed distributions to a Non-U.S. Holder and, if there is no associated cash payment, may set off its withholding obligations against other payments to or funds of such holder and (iv) we are required to report the amount of any deemed distributions on our website or to the IRS and all holders of warrants (including holders of warrants that would otherwise be exempt from reporting). The final regulations will be effective for deemed distributions occurring on or after the date of adoption, but holders of warrants and withholding agents may rely on them prior to that date under certain circumstances.

Distributions

Distributions on our common stock or pre-funded warrants made to a Non-U.S. Holder will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a Non-U.S. Holder's adjusted tax basis in our common stock or pre-funded warrant, as applicable. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock or pre-funded warrant as described below under the section titled *Gain on Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants*.

Any distribution on our common stock or pre-funded warrants that is treated as a dividend paid to a Non-U.S. Holder (including constructive distributions or dividend equivalents deemed paid) that is not effectively connected with the holder's conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder's country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid (or constructive dividends or dividend equivalents deemed paid) to a Non-U.S. Holder that are effectively connected with the holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to the applicable withholding agent). In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional branch profits tax, which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

See also the section below titled *Foreign Accounts* for additional withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial foreign entities.

Gain on Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants

Subject to the discussions below under the sections titled *Backup Withholding and Information Reporting* and *Foreign Accounts*, a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock, pre-funded warrant or common warrants unless (a) the gain is effectively connected with a trade or business of the holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that the holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more

days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a United States real property holding corporation within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or the holder's holding period in the common stock, pre-funded warrants or common warrants.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at the regular graduated U.S. federal income tax rates applicable to U.S. persons. Corporate Non-U.S. Holders described in (a) above may also be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by certain U.S. source capital losses, provided you have timely filed U.S. federal income tax returns with respect to such losses. With respect to (c) above, in general, we would be a United States real property holding corporation if U.S. real property interests as defined in the Code and the Treasury Regulations comprised (by fair market value) at least half of our assets. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation. However, there can be no assurance that we will not become a United States real property holding corporation in the future. Even if we are treated as a U.S. real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock, pre-funded warrants or common warrants will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly or constructively, no more than five percent of our common stock and pre-funded warrants at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will qualify as regularly traded on an established securities market.

See the section titled *Foreign Accounts* for additional information regarding withholding rules that may apply to proceeds of a disposition of our common stock, pre-funded warrants or common warrants paid to foreign financial institutions or non-financial foreign entities.

Backup Withholding and Information Reporting

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock and pre-funded warrants including the amount of any such dividends (including constructive distributions or dividend equivalents deemed paid), the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder (including constructive distributions or dividend equivalents deemed paid) may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable, or otherwise establishes an exemption, provided that the applicable withholding agent does not have actual knowledge or reason to know the holder is a U.S. person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock, pre-funded warrants or common warrants effected by or through a U.S. office of any broker, U.S. or non-U.S., unless the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable, or otherwise meets documentary evidence requirements for establishing non-U.S. person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. If backup withholding is applied to you, you should consult with your own tax advisor to determine whether you have overpaid your U.S. federal income tax, and whether you are able to obtain a tax refund or credit of the overpaid amount.

Foreign Accounts

In addition, U.S. federal withholding taxes may apply under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments, including dividends, constructive dividends or dividend equivalents deemed paid and, on or after January 1, 2019, the gross proceeds of a disposition of our common stock, pre-funded warrants or common warrants, paid to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including constructive dividends and dividend equivalents) on, or, on or after January 1, 2019, gross proceeds from the sale or other disposition of, our common stock, pre-funded warrants or

common warrants paid to a foreign financial institution or a non-financial foreign entity (each as defined in the Code), unless (1) the foreign financial institution agrees to undertake certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any substantial United States owners (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. The 30% federal withholding tax described in this paragraph cannot be reduced under an income tax treaty with the United States. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain specified United States persons or United States-owned foreign entities (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock, pre-funded warrants or common warrants.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK OR PRE-FUNDED WARRANTS, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS SUCH AS ESTATE AND GIFT TAX.

UNDERWRITING

We have entered into an underwriting agreement, dated May 2, 2018, with A.G.P., acting as the representative of the several underwriters named below, with respect to the shares of common stock and the accompanying common warrants, and the pre-funded warrants and the accompanying common warrants subject to this offering. Subject to certain conditions, we have agreed to sell to the underwriters, and the underwriters have severally agreed to purchase, the number of shares of common stock and the accompanying common warrants, and the pre-funded warrants and the accompanying common warrants provided below opposite their respective names.

Underwriters	Number of Shares	Number of Pre-Funded Warrants	Number of Common Warrants
A.G.P.	2,700,000	8,550,000	5,625,000
CIM Securities, LLC	300,000	950,000	625,000
Total	3,000,000	9,500,000	6,250,000

The underwriters are offering the shares of common stock and the accompanying common warrants and the pre-funded warrants and the accompanying common warrants subject to their acceptance of the shares of common stock, common warrants and the pre-funded warrants from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock and the accompanying common warrants and the pre-funded warrants and the accompanying common warrants offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock and the accompanying common warrants and the pre-funded warrants and the accompanying common warrants if any such shares and the accompanying common warrants and pre-funded warrants and the accompanying common warrants are taken.

Discount, Commissions and Expenses

The underwriters have advised us that they propose to offer the shares of common stock and the accompanying common warrants and the pre-funded warrants and the accompanying common warrants to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$0.0504 per share of common stock and the accompanying common warrants and pre-funded warrant and the accompanying common warrants. After this offering, the public offering price and concession may be changed by the representative. No such change shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The shares of common stock and the accompanying common warrants and the pre-funded warrants and the accompanying common warrants are offered by the underwriters as stated herein, subject to receipt

and acceptance by them and subject to their right to reject any order in whole or in part. The underwriters have informed us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

The following table shows the underwriting discount payable to the underwriters by us in connection with this offering.

	Per Share	Per Pre-Funded Warrant	Per Common Warrant	Total Without Over-Allotment	Total With Over-Allotment
Public offering price	\$ 1.44	\$ 1.43	\$ 0.01	\$ 17,967,500	\$ 20,676,875
Underwriting discount	\$ 0.1008	\$ 0.1001	\$ 0.0007	\$ 1,257,725	\$ 1,447,381
Proceeds, before expenses, to us	\$ 1.3392	\$ 1.3299	\$ 0.0093	\$ 16,709,775	\$ 19,229,494

We have agreed to reimburse the underwriters for certain out-of-pocket expenses not to exceed \$150,000 in the aggregate without our consent which shall not be unreasonably withheld. We estimate that expenses payable by us in connection with this offering, including reimbursement of the underwriters out-of-pocket expenses, but excluding the underwriting discount referred to above, will be approximately \$500,000.

Over-allotment Option

We have granted to the underwriters an option exercisable not later than 45 days after the date of this prospectus to purchase up to 1,875,000 additional shares of common stock and/or additional common warrants to purchase up to 937,500 shares of common stock at the public offering price per share of common stock and/or common warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover overallotments, if any, made in connection with this offering. If any additional shares of common stock and/or common warrants are purchased pursuant to the over-allotment option, the underwriters will offer these shares of common stock and/or common warrants on the same terms as those on which the other securities are being offered.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Lock-up Agreements

We, our officers and directors have agreed, subject to limited exceptions, for a period of 90 days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of the representative. The representative may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

The underwriters have advised us that they do not intend to conduct any stabilization or over-allotment activities in connection with this offering.

Passive Market Making

In connection with this offering, the underwriters and any selling group members may engage in passive market making transactions in our common stock on the NASDAQ Stock Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriters, or by their affiliates. Other than this prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other

From time to time, certain of the underwriters and/or their affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services they have received and, may in the future receive, customary fees. In the course of their businesses, the underwriters and their affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriters and their affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering, no underwriter has provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain any underwriter to perform any investment banking or other financial services for at least 90 days after the date of this prospectus.

NOTICE TO INVESTORS

Notice to Investors in the United Kingdom

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State) an offer to the public of any securities which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any such securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a)

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b)

to any legal entity which has two or more of: (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

(c)

by the underwriter to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or

(d)

in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of these securities shall result in a requirement for the publication by the issuer or the underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any such securities to be offered so as to enable an investor to decide to purchase any such securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each underwriter has represented, warranted and agreed that:

(a)

it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of any of the securities in circumstances in which section 21(1) of the FSMA does not apply to the issuer; and

(b)

it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

European Economic Area

In particular, this document does not constitute an approved prospectus in accordance with European Commission’s Regulation on Prospectuses no. 809/2004 and no such prospectus is to be prepared and approved in connection with this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (being the Directive of the European Parliament and of the Council 2003/71/EC and including any relevant implementing measure in each Relevant Member State) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) an offer of securities to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to such securities which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of securities to the public in that Relevant Member State at any time:

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

.
to any legal entity which has two or more of: (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in the last annual or consolidated accounts; or

in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of securities to the public” in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. For these purposes the securities offered hereby are “securities.”

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Gracin & Marlow, LLP, New York, New York. Zysman, Aharoni, Gayer and Sullivan & Worcester LLP, is acting as counsel to the underwriters in this offering.

EXPERTS

The financial statements as of December 31, 2017 and 2016 and for each of the two years in the period ended December 31, 2017 incorporated by reference in this Prospectus and in the Registration Statement have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated by reference in this Prospectus and in the Registration Statement, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and the securities offered hereby, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

You may read and copy all or any portion of the registration statement without charge at the public reference room of the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the Securities and Exchange Commission at prescribed rates from the public reference room of the Securities and Exchange Commission at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, registration statements and certain other filings made with the Securities and Exchange Commission electronically are publicly available through the Securities and Exchange Commission's website at www.sec.gov. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the Securities and Exchange Commission. You may also read all or any portion of the registration statement and certain other filings made with the Securities

and Exchange Commission on our website at www.heatbio.com. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

We are subject to the information and periodic reporting requirements of the Exchange Act and, accordingly, are required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the Securities and Exchange Commission. You will be able to inspect and copy such periodic reports, proxy statements and other information at the Securities and Exchange Commission's public reference room, the website of the Securities and Exchange Commission referred to above, and our website at www.heatbio.com. Except for the specific incorporated reports and documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” certain information that we will file with it which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (Commission File No. 001-35994) after (i) the date of this initial registration statement and prior to effectiveness of this registration statement and (ii) the date of this prospectus and before the completion of the offering of the securities included in this prospectus, however, we will not incorporate by reference any documents or portions thereof that are not deemed “filed” with the SEC, or any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K:

- Our Annual Report on Form 10-K for the year ended December 31, 2017 (Commission File No. 001-35994) filed with the SEC on March 2, 2018;
- Our Current Reports on Form 8-K (Commission File No. 001-35994) filed with the SEC on January 10, 2018, January 19, 2018 (regarding the sales agreement), January 19, 2018 (regarding the reverse stock split), February 7, 2018, February 20, 2018, February 28, 2018, March 6, 2018, March 12, 2018, March 19, 2018, March 26, 2018, and April 20, 2018;
- Our Definitive Proxy Statement on Schedule 14A filed with the SEC on May 11, 2017;
- The description of our common stock set forth in our registration statement on Form 8-A, filed with the SEC on July 8, 2013 (Commission File No. 001-35994); and
- The description of our common stock purchase rights set forth in our registration statement on Form 8-A, filed with the SEC on March 12, 2018 (Commission File No. 001-35994).

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that we incorporate by reference in this prospectus contained in the registration statement (except exhibits to the documents that are not specifically incorporated by reference) at no cost to you, by writing or calling us at the following address and telephone number:

Heat Biologics, Inc.

801 Capitola Drive, Suite 12
Durham, North Carolina 27713

(919) 240-7133

Information about us is available at our website at www.heatbio.com. Except for the specific incorporated reports and documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part. Any statement contained in this registration statement

or in a document incorporated or deemed to be incorporated by reference in this registration statement shall be deemed to be modified or superseded for purposes of this registration statement to the extent that a statement contained in this registration statement or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this registration statement modifies or supersedes that statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this registration statement.

3,000,000 Shares of Common Stock

Pre-Funded Warrants to Purchase 9,500,000 Shares of Common Stock

Common Warrants to Purchase 6,250,000 Shares of Common Stock

PROSPECTUS

A.G.P.

Offering Securities Through Euro Pacific Capital Inc.

CIM Securities, LLC

May 2, 2018

Through and including June 1, 2018 (25 days after commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.