HEAT BIOLOGICS, INC. Form 10-Q November 14, 2018

# **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

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# QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

OR

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_ Commission file number: 001-35994

Heat Biologics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of

Incorporation or Organization)

26-2844103

(I.R.S. Employer

Identification No.)

# **801** Capitola Drive

**Durham**, NC

# 27713

(Address of Principal Executive Offices)

(Zip Code)

#### (919) 240-7133

(Registrant s Telephone Number, including Area Code)

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

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

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

Large accelerated filer		Accelerated filer	
Non-accelerated filer	þ	Smaller reporting company	þ
		Emerging growth company	þ

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

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

As of November 12, 2018, there were 23,257,144 shares of Common Stock, \$0.0002 par value per share, outstanding.

# HEAT BIOLOGICS, INC.

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# **SIGNATURES**

#### FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act ), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ). All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words anticipate. believe, estimate, expect. intend, may, plan. predict, project. target. potential. will continue and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are not guarantees of future performance and our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, our ability to raise additional capital to support our clinical development program and other operations, our ability to develop products of commercial value and to identify, discover and obtain rights to additional potential product candidates, our ability to protect and maintain our intellectual property and the ability of our licensors to obtain and maintain patent protection for the technology or products that we license from them, the outcome of research and development activities, our reliance on third-parties, competitive developments, the effect of current and future legislation and regulation and regulatory actions, as well as other risks described more fully in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission (the SEC). Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A. Risk Factors and elsewhere herein and those identified under Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 2, 2018. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

As a result of these and other factors, we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

#### NOTE REGARDING COMPANY REFERENCES

Throughout this Quarterly Report on Form 10-Q, Heat Biologics, the Company, we and our refer to Heat Biologics Inc.

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# PART I FINANCIAL INFORMATION

# ITEM 1.

# FINANCIAL STATEMENTS

# HEAT BIOLOGICS, INC.

# **Consolidated Balance Sheets**

	i	September 30,		December 31,
Current Assets		2018 (unaudited)		2017
Cash and cash equivalents	\$	20,962,319	\$	9,763,067
Accounts receivable	φ	68,238	φ	14,833
Prepaid expenses and other current assets		2,477,751		1,967,257
Total Current Assets		23,508,308		11,745,157
Total Current Assets		25,500,500		11,745,157
Property and Equipment, net		663,065		286,891
Other Assets				
Restricted cash				2,292
In-process R&D		5,866,000		5,866,000
Goodwill		2,189,338		2,189,338
Deposits		99,220		69,798
Deferred financing costs				30,000
Total Other Assets		8,154,558		8,157,428
Total Assets	\$	32,325,931	\$	20,189,476
Liabilities and Stockholders Equity				
Current Liabilities				
Accounts payable	\$	976,090	\$	1,033,680
Deferred revenue		3,090,675		6,826,388
Contingent consideration		1,217,000		
Accrued expenses and other liabilities		1,530,820		2,276,431
Total Current Liabilities		6,814,585		10,136,499
Long Term Liabilities				
Other long term liabilities		188,482		160,559
Deferred tax liability		637,140		1,302,220
Deferred revenue, net of current portion		200,000		200,000

Edgar Filing: HEAT BIOLOGICS, INC Form 10-Q						
Contingent consideration, net of current portion Total Liabilities		2,058,225 9,898,432	2,609,289 14,408,567			
Commitments and Contingencies						
Stockholders Equity						
Common stock, \$.0002 par value; 100,000,000 shares authorized,						
23,235,596 and 4,200,310 shares issued and outstanding at						
September 30, 2018 (unaudited) and December 31, 2017,						
respectively		4,647	840			
Additional paid-in capital		104,378,324	76,382,262			
Accumulated deficit		(79,642,034)	(68,846,326)			
Accumulated other comprehensive loss		(55,377)	(166,025)			
Total Stockholders Equity Heat Biologics, Inc.		24,685,560	7,370,751			
Non-Controlling Interest		(2,258,061)	(1,589,842)			
Total Stockholders Equity		22,427,499	5,780,909			
Total Liabilities and Stockholders Equity	\$	32,325,931 \$	20,189,476			

See Notes to Financial Statements

# HEAT BIOLOGICS, INC.

# **Consolidated Statements of Operations and Comprehensive Loss**

# (Unaudited)

	Three Mont Septemb	ed,	Nine Months Ended, September 30,			
	2018	2017	2018	-	2017	
Revenue: Grant and licensing revenue	\$ 1,840,009	\$ \$ 470,823	3,735,713	\$	906,313	
Operating expenses: Research and						
development General and	4,403,759	1,823,922	10,756,485		5,788,755	
administrative Change in fair value of contingent	1,585,600	1,188,476	4,727,105		4,298,072	
consideration Total operating	114,838		665,936			
expenses	6,104,197	3,012,398	16,149,526		10,086,827	
Loss from operations	(4,264,188)	(2,541,575)	(12,413,813)		(9,180,514)	
Interest income	83,509	5,629	131,306		17,316	
Other income, net Total non-operating	31,704	31,768	153,500		109,211	
income, net	115,213	37,397	284,806		126,527	
Net loss before income tax benefit Income tax	(4,148,975)	(2,504,178)	(12,129,007)		(9,053,987)	
benefit	225,389		665,080			
Net loss Net loss non-controlling	(3,923,586)	(2,504,178)	(11,463,927)		(9,053,987)	
interest	(265,024)	(203,371)	(668,219)		(344,328)	
Net loss attributable to Heat Biologics,	\$ (3,658,562)	\$ (2,300,807) \$	(10,795,708)	\$	(8,709,659)	

Inc.

me.				
Net loss per share attributable to Heat Biologics, Inc. basic and diluted	\$ (0.16)	\$ (0.64) \$	(0.75)	\$ (2.66)
Weighted-average number of common shares used in net loss per share attributable to common stockholders basic and diluted	23,143,952	3,578,661	14,359,429	3,269,536
Other comprehensive loss:				
Net loss Unrealized gain /(loss) on foreign currency	(3,923,586)	(2,504,178)	(11,463,927)	(9,053,987)
translation Total other comprehensive	39,377	(24,707)	110,648	(100,742)
loss Comprehensive loss attributable to non-controlling	(3,884,209)	(2,528,885)	(11,353,279)	(9,154,729)
interest	(265,024)	(203,371)	(668,219)	(344,328)
Comprehensive loss	\$ (3,619,185)	\$ (2,325,514) \$	(10,685,060)	\$ (8,810,401)

See Notes to Financial Statements

# HEAT BIOLOGICS INC.

# Consolidated Statements of Stockholders Equity

# (Unaudited)

	Co	ommon		٨	ccumulated C		cumulated Other prebensiv <b>a</b> lo	n-Controlling	Total Stockholders
		Stock	APIC	Л	Deficit	/0111	Loss	Interest	Equity
Balance at December 31,									
<b>2017</b> Public offering, 14,375,000 shares, net of underwriters	\$	840	\$ 76,382,262	\$	(68,846,326)	\$	(166,025)\$	(1,589,842) \$	5,780,909
discount Exercise of warrants, 3,054,667		2,875	20,697,122						20,699,997
shares Issuance of common stock, 1,545,449		611	4,837,982						4,838,593
shares Stock issuance		309	3,866,096						3,866,405
costs Stock-based			(2,057,872)						(2,057,872)
compensation Other comprehensive		12	652,734						652,746
gain Net loss Balance at September 30,					(10,795,708)		110,648	(668,219)	110,648 (11,463,927)
2018	\$	4,647	\$ 104,378,324	\$	(79,642,034)	\$	(55,377) \$	(2,258,061) \$	22,427,499

See Notes to Financial Statements

# HEAT BIOLOGICS, INC.

# **Consolidated Statements of Cash Flows**

# (Unaudited)

	Nine months Ended September 30			
		2018		2017
Cash Flows from Operating Activities				
Net loss	\$	(11,463,927)	\$	(9,053,987)
Adjustments to reconcile net loss to net cash used in				
operating activities:				
Depreciation		171,235		100,958
Stock-based compensation		652,746		546,321
Change in fair value of contingent consideration		665,936		
Increase (decrease) in cash arising from changes in assets				
and liabilities:				
Accounts receivable		(53,714)		81,185
Prepaid expenses and other current assets		(514,265)		(1,592,084)
Accounts payable		(55,384)		4,179
Deferred revenue		(3,735,713)		938,388
Accrued expenses and other liabilities		(743,519)		(475,350)
Deferred tax liability		(665,080)		
Deferred financing costs		30,000		(46,340)
Other long term liabilities		27,923		(11,464)
Deposits		(29,422)		
Net Cash Used in Operating Activities		(15,713,184)		(9,508,194)
Cash Flows from Investing Activities				
Purchase of Pelican, net of cash acquired				(468,801)
Purchase of property and equipment		(547,409)		(61,382)
Net Cash Used in Investing Activities		(547,409)		(530,183)
Cash Flows from Financing Activities				
Proceeds from public offering, net of underwriting				
discounts		20,699,997		4,183,000
Proceeds from the issuance of common stock, net of				
commissions		3,866,405		2,463,180
Proceeds from exercise of warrants		4,838,593		
Stock issuance costs		(2,057,872)		(239,617)
Net Cash Provided by Financing Activities		27,347,123		6,406,563
		110,430		(21,105)

Effect of exchange rate changes on cash, cash equivalents and restricted cash		
Net Increase/(Decrease) in Cash, Cash Equivalents and Restricted Cash	11,196,960	(3,652,919)
Cash, Cash Equivalents and Restricted Cash Beginning of Period	9,765,359	7,943,838
Cash, Cash Equivalents and Restricted Cash End of Period	\$ 20,962,319	\$ 4,290,919
<b>Supplemental Disclosure for Cash Flow Information</b> Issuance of common stock for purchase of Pelican	\$	\$ 1,052,000

See Notes to Financial Statements

# HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

# 1. Basis of Presentation and Significant Accounting Policies

#### Basis of Presentation and Principles of Consolidation

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

The accompanying unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial reporting. However, certain information or footnote disclosures normally included in complete financial statements prepared in accordance with U.S. GAAP have been condensed, or omitted, pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). In the opinion of the Company s management, the unaudited consolidated financial statements in this Quarterly Report on Form 10-Q include all normal and recurring adjustments necessary for the fair statement of the results for the interim periods presented. The results for the nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2018.

The consolidated financial statements as of and for the nine months ended September 30, 2018 and 2017 included in this Quarterly Report on Form 10-Q are unaudited. The balance sheet as of December 31, 2017 is derived from the audited consolidated financial statements as of that date. The accompanying unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes, together with Management s Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 2, 2018

(the 2017 Annual Report ).

On April 28, 2017, the Company completed the acquisition of an 80% controlling interest in Pelican Therapeutics, Inc. (Pelican), a related party prior to acquisition. Operations of Pelican are included in the consolidated statements of operations and comprehensive loss from the acquisition date.

The accompanying consolidated financial statements as of and for the nine months ended September 30, 2018 and 2017 include the accounts of Heat Biologics, Inc. (the Company), and its subsidiaries, Heat Biologics I, Inc. (Heat I), Heat Biologics III, Inc. (Heat III), Heat Biologics IV, Inc. (Heat IV), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd. and Zolovax. Additionally, as of the nine months ended September 30, 2018 the accompanying consolidated financials include Pelican. The functional currency of the entities located outside the United States is the applicable local currency (the foreign entities). Assets and liabilities of the foreign entities are translated at period-end exchange rates. Statement of operations accounts are translated at the average exchange rate during the period. The effects of foreign currency translation adjustments are included in other comprehensive loss, which is a component of accumulated other comprehensive loss in stockholders equity. All significant intercompany accounts and transactions have been eliminated in consolidation. At December 31, 2017 and September 30, 2018, the Company held a 92.5% controlling interest in Heat I and an 80% controlling interest in Pelican. All other subsidiaries are wholly owned. For the nine months ended September 30, 2018 the Company recognized \$223,487 in net loss non-controlling interest for Heat I and \$444,732 in net loss non-controlling interest for Pelican. The Company accounts for its less than 100% interest in these subsidiaries in the consolidated financial statements in accordance with U.S. GAAP. Accordingly, the Company presents non-controlling interests as a component of stockholders equity on its consolidated balance sheets and reports non-controlling interest net loss under the heading net loss non-controlling interest in the consolidated statements of operations and comprehensive loss.



#### **HEAT BIOLOGICS, INC.**

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The Company has an accumulated deficit of approximately \$79.6 million as of September 30, 2018 and a net loss of approximately \$11.5 million for the nine months ended September 30, 2018 and has not generated significant revenue or positive cash flows from operations. The Company expects to incur significant expenses and continued losses from operations for the foreseeable future. The Company expects its expenses to increase in connection with its ongoing activities, particularly as the Company continues its research and development and advances its clinical trials of, and seek marketing approval for, its product candidates and as the Company continues to fund the Pelican matching funds required in order to access the CPRIT Grant. In addition, if the Company obtains marketing approval for any of its product candidates, the Company expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, the Company will need to obtain substantial additional funding in connection with its continuing operations. Adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts. To meet its capital needs, the Company intends to continue to consider multiple alternatives, including, but not limited to, additional equity financings such as sales of its common stock under the H.C. Wainwright Sales Agreement if available, debt financings, partnerships, collaborations and other funding transactions. This is based on the Company s current estimates, and the Company could use its available capital resources sooner than it currently expects. The Company is continually evaluating various cost-saving measures in light of its cash requirements in order to focus resources on its product candidates. The Company will need to generate significant revenues to achieve profitability, and it may never do so. As of September 30, 2018, the Company had approximately \$21.0 million in cash and cash equivalents and has sufficient cash on hand to fund its operations one year from date of this filing.

In May 2018, through a public offering, the Company raised approximately \$18.8 million, net of underwriting discounts and commissions and other estimated offering expenses, and an additional \$4.8 million through the exercise of 3,054,667 warrants. On April 28, 2017, the acquisition of an 80% controlling interest in Pelican, a related party prior to acquisition, was completed. Pelican has been awarded a \$15.2 million grant to fund preclinical and some clinical activities from the Cancer Prevention and Research Institute of Texas ( CPRIT ). The CPRIT grant is subject to customary CPRIT funding conditions. The Company believes the acquisition aligns its strategic focus and strengthens its position in the T-cell activation arena.

#### Cash Equivalents and Restricted Cash

The Company considers all highly liquid instruments with an original maturity of three months or less to be cash equivalents. Restricted cash consists of deposits held by the US Patent and Trademark Office.

# Use of Estimates

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

#### Segments

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

# **Business Combinations**

The Company accounts for acquisitions using the acquisition method of accounting, which requires that all identifiable assets acquired and liabilities assumed be recorded at their estimated fair values. The excess of the fair value of purchase consideration over the fair values of identifiable assets and liabilities is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions.

Critical estimates in valuing certain intangible assets include but are not limited to future expected cash flows from acquired patented technology. Management s estimates of fair value are based upon assumptions believed to be reasonable, but are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Other estimates associated with the accounting for acquisitions may change as additional information becomes available regarding the assets acquired and liabilities assumed (see Note 2).

# HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

#### Goodwill and In-Process Research and Development

The Company classifies intangible assets into three categories: (1) intangible assets with definite lives subject to amortization, (2) intangible assets with indefinite lives not subject to amortization and (3) goodwill. The Company determines the useful lives of definite-lived intangible assets after considering specific facts and circumstances related to each intangible asset. Factors the Company considers when determining useful lives include the contractual term of any agreement related to the asset, the historical performance of the asset, and other economic facts; including competition and specific market conditions. Intangible assets that are deemed to have definite lives are amortized, primarily on a straight-line basis, over their estimated useful lives.

Intangible assets that are deemed to have indefinite lives, including goodwill, are reviewed for impairment annually on the anniversary of the acquisition, or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment test for indefinite-lived intangibles, other than goodwill, consists of a comparison of the fair value of the intangible asset with its carrying amount. If the carrying amount exceeds the fair value, an impairment charge is recognized in an amount equal to that excess. Indefinite-lived intangible assets, such as goodwill, are not amortized. The Company will qualitatively test the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence a potential impairment exists, using a fair value-based test. No impairment existed at September 30, 2018.

In-process research and development, or IPR&D, assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D assets represent the fair value assigned to technologies that the Company acquires, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval and the ability to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value. No impairment existed at September 30, 2018.

#### **Contingent Consideration**

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain milestones in the future ( contingent consideration ). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations. The Company estimates the fair value of the contingent consideration as of the acquisition date using the estimated future cash outflows based on the probability of meeting future milestones. The milestone payments will be made upon the achievement of clinical and commercialization milestones as well as single low digit royalty payments and payments upon receipt of sublicensing income. Subsequent to the date of acquisition, the Company will reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations (see Note 2).

# **Revenue Recognition**

Effective January 1, 2018, the Company has adopted on a modified retrospective basis Accounting Standards Codification (ASC) Topic 606.

The Company s sole source of current revenue is grant revenue related to the CPRIT Contract, which is being accounted for under ASC 606. ASC 606 introduces a new framework for analyzing potential revenue transactions by identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations in the contract, and recognizing revenue when (or as) the Company satisfies a performance obligation.

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# HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The performance obligations of the CPRIT Contract include developing a human TNFRSF25 agonist antibody for use in cancer patients through research and development efforts and a noncommercial license from CPRIT-funded research to CPRIT and other government agencies and institutions of higher education in Texas.

Management has concluded that the license and R&D services should be combined into a single performance obligation as both are highly interdependent - a license cannot be effectively granted without the corresponding research basis and CPRIT cannot benefit from the license without the R&D services and are therefore not capable of being distinct.

The CPRIT grant covers a period from June 1, 2017 through October 31, 2019, for a total grant award of up to \$15.2 million. CPRIT advances grant funds upon request by the Company consistent with the agreed upon amounts and schedules as provided in the contract. The first tranche of funding of \$1.8 million was received in May 2017, and a second tranche of funding of \$6.5 million was received in October 2017. The next tranche of funding is expected to be requested and received in the next few months. Funds received are reflected in deferred revenue as a liability until revenue is earned. Grant revenue is recognized when qualifying costs are incurred.

#### **Deferred** Revenue

As of September 30, 2018, deferred revenue balance is \$3.1 million received from CPRIT for which the costs have not been incurred or the conditions of the award have not been met and \$0.2 million of grant funds received from an economic development grant agreement with the City of San Antonio (Economic Development Grant), for the purpose of defraying costs toward the purchase of laboratory equipment. As of September 30, 2018, \$5.2 million was recognized as revenue from CPRIT since the CPRIT contract inception.

#### Prepaid Expenses and Other Current Assets

The Company s prepaid expenses and other current assets consists primarily of the amount paid in advance for cGMP production of Pelican s PTX-35 antibody and other Tumor Necrosis Factor Receptor Super Family member

25( TNFRSF25 ) target biologics, as well as Chemistry Manufacturing and Control ( CMC ) material for the Company s clinical trial studies for HS-110.

# Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities, using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent that utilization is not presently more likely than not.

# Significant Accounting Policies

The significant accounting policies used in preparation of these interim financial statements are disclosed in the Company's Form 10-K and have not changed significantly since such filing.

#### **Recently Issued Accounting Pronouncements**

In June 2018, the FASB issued ASU 2018-07: *Compensation* Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, early adoption is permitted but no earlier than an entity s adoption date of Topic 606. The Company has not determined the impact of this standard and does not plan early adoption of this standard.

# HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

In August 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230) Restricted Cash. ASU 2016-18 requires the statement of cash flows to be a reconciliation between beginning and ending cash balances inclusive of restricted cash balances. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and is to be applied using a retrospective transition method to each period presented. The Company adopted this ASU for the year ending December 31, 2018. The adoption of this standard resulted in the removal of changes in Restricted Cash from the Consolidated Statements of Cash Flows of \$2,292 and \$98,879 for the nine months ended September 30, 2018 and 2017, respectively and inclusion of these amounts as part of the starting and ending cash balances.

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

#### Classification of Certain Items Within the Company s Form 10-K

Certain reclassifications of prior period amounts will be made within the Company s Form 10-K filing for the year ended December 31, 2018 to conform to current period presentation. Specifically, during the nine months ended September 30, 2018, the Company determined that \$200,000 related to deferred revenue should have been classified as long term rather than short term. There is no impact to the consolidated statements of operations or consolidated balance sheets. The Company evaluated the effect of this misclassification and concluded it was not material to any of

its previously issued consolidated financial statements.

#### Immaterial Error Correction

Certain error corrections will be made within the Company s Form 10-Q filings for the quarters ended March 31, 2019 and June 30, 2019 to conform to current period presentation. During the nine months ended September 30, 2018, the Company determined that an income tax benefit was required for the quarters ended March 31, 2018 and June 30, 2018. Specifically, the current year net operating losses gave rise to an indefinite-lived deferred tax asset which provided sufficient support to offset up to 80% of the Company s indefinite-lived deferred tax liability. Accordingly, the income tax benefit for the quarters ended March 31, 2018 and June 30, 2018 were understated by approximately \$205,000 and \$235,000, respectively. The Company evaluated the effect of this error and concluded it was not material to any of its previously issued consolidated financial statements. Upon revision, the Company will have an income tax benefit of approximately \$205,000 and \$235,000 for the quarters ended March 31, 2018 and June 30, 2018, respectively. There is no impact of this error for any quarters prior to March 31, 2018.

# HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

#### 2. Acquisition of Pelican Therapeutics

On April 28, 2017, the Company consummated the acquisition of 80% of the outstanding equity of Pelican, a related party, and Pelican became a majority owned subsidiary of the Company. Operations of Pelican are included in the consolidated statements of operations and comprehensive loss from the acquisition date. Pelican is a biotechnology company focused on the development and commercialization of monoclonal antibody and fusion protein-based therapies that are designed to activate the immune system. In exchange for 80% of the outstanding capital stock of Pelican on a fully diluted basis, the Company paid to the Pelican Stockholders that executed the Stock Purchase Agreement (the Participating Pelican Stockholders ) an aggregate of \$0.5 million minus certain liabilities (the Cash Consideration ), and issued to the Participating Pelican Stockholders 133,106 shares of the Company s restricted common stock representing 4.99% of the outstanding shares of our common stock on the date of the initial execution of the Purchase Agreement (the Stock Consideration ). During the nine months ended September 30, 2018, the Cash Consideration of approximately \$0.3 million was distributed to the Participating Pelican Stockholders and the remainder of approximately \$0.2 million for certain Pelican liabilities not satisfied was recognized as other income in the Consolidated Statements of Operations and Comprehensive Loss.

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

(1)

\$2,000,000 upon Pelican s dosing of the first patient in its first Phase 1 trial for an oncology indication;

(2)

\$1,500,000 upon Pelican s dosing of the first patient in its first Phase 2 trial for an oncology indication;

(3)

\$3,000,000 upon successful outcome of the first Phase 2 trial for an oncology indication;

(4)

\$6,000,000 upon Pelican s dosing of the first patient in its first Phase 3 trial for an oncology indication;

(5)

\$3,000,000 upon Pelican s dosing of the first patient in its first Phase 3 trial for a non- oncology indication;

(6)

\$7,500,000 upon successful outcome of the first Phase 3 trial for an oncology indication;

(7)

\$3,000,000 upon successful outcome of the first Phase 3 trial for a non-oncology indication;

(8)

\$7,500,000 upon acceptance of a Biologics License Application (BLA) submission for an oncology indication;

(9)

\$3,000,000 upon acceptance of a BLA submission for a non-oncology indication;

(10)

\$7,500,000 upon first product indication approval in the United States or Europe for an oncology indication;

(11)

\$3,000,000 upon first product indication approval in the United States or Europe for a non-oncology indication.

The fair value of these future milestone payments is reflected in the contingent consideration account under long term liabilities on the balance sheet. The estimated fair value of the contingent consideration was determined using a probability-weighted income approach, at a discount of 5.51% based on the median yield of publicly traded non-investment grade debt of companies in the pharmaceutical industry. The Company performs an analysis on a quarterly basis and as of September 30, 2018, the Company determined the change in the estimated fair value of the contingent consideration was \$665,936 for the nine months ended September 30, 2018.

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

# HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

Aggregate consideration: Cash consideration Stock consideration	\$ \$	500,000 1,052,000
Contingent consideration Total Consideration	\$ <b>\$</b>	2,385,000 <b>3,937,000</b>
Purchase price allocation:		
Cash acquired	\$	31,199
In-process R&D	\$	5,866,000
Goodwill	\$	2,189,338
Deferred tax liability	\$	(2,111,760)
Net liabilities assumed	\$	(1,102,777)
Fair value of non-controlling interest	\$	(935,000)
Total purchase price	\$	3,937,000

Goodwill is calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill resulting from this acquisition arises largely from synergies expected from combining the operations. The goodwill is not deductible for income tax purposes.

In-process R&D assets are treated as indefinite-lived until the completion or abandonment of the associated R&D program, at which time the appropriate useful lives will be determined.

The Company calculated the fair value of the non-controlling interest acquired in the acquisition as 20% of the equity interest of Pelican, adjusted for a minority interest discount.

In May 2016, Pelican was awarded a \$15.2 million grant from CPRIT for development of Pelican s lead product candidate, PTX-35. The CPRIT Grant is expected to allow Pelican to develop PTX-35 through a 70-patient Phase 1 clinical trial. The Phase 1 clinical trial will be designed to evaluate PTX-35 in combination with other immunotherapies. The CPRIT Grant is subject to customary CPRIT funding conditions including a matching funds

requirement where Pelican will match \$0.50 for every \$1.00 from CPRIT. Consequently, Pelican is required to raise \$7.6 million in matching funds over the three year project.

Pelican has contributed net revenue of \$3.7 million and net loss of \$2.2 million, respectively, which are included in the Company s consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2018.

#### HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The following unaudited pro forma information presents the combined results of operations for the nine months ended September 30, 2017, as if the Company had completed the Pelican acquisition at the beginning of fiscal 2017. All expenses for Pelican have been included in the Company s consolidated financials since the quarter ending September 30, 2017, therefore the nine months ended September 30, 2018 are not pro forma and the three months ended September 30, 2018 and 2017 are not applicable. The pro forma financial information is provided for comparative purposes only for the nine months ended September 30, 2017 and is not necessarily indicative of what actual results would have been had the acquisition occurred on the date indicated, nor does it give effect to synergies, cost savings, fair market value adjustments, immaterial amortization expense and other changes expected to result from the acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period.

#### **Nine Months Ended**

	September 30,				
		2018	2017		
Revenue	\$	3,735,713	\$ 906,313		
Net loss		(11,463,927)	(9,444,913)		
Net loss: Non-controlling interest		(668,219)	(422,513)		
Net loss attributable to Heat Biologics, Inc.	\$	(10,795,708)	\$ (9,022,400)		
Net loss per share attributable to Heat Biologics, Inc. basic and					
diluted	\$	(0.75)	\$ (2.65)		

#### **3.** Fair Value of Financial Instruments

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

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

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

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

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

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the entire fair value measurement requires management to make judgments and consider factors specific to the asset or liability. The Company's cash equivalents are classified within Level I of the fair value hierarchy.

The following table provides a rollforward of the Company s Level 3 fair value measurements:

	Contingent		
	Co	nsideration	
Balance at December 31, 2017	\$	2,609,289	
Change in fair value		665,936	
Balance at September 30, 2018	\$	3,275,225	

The change in the fair value of the contingent consideration of \$665,936 for the nine months ended September 30, 2018 reflects an increase in the probability of reaching Pelican s dosing of the first patient in its first Phase 1 trial for an oncology indication based on the passage of time and impact of progress in antibody manufacturing. Adjustments associated with the change in fair value of contingent consideration are included in the Company s consolidated statement of operations and comprehensive loss.

# HEAT BIOLOGICS, INC.

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The following table presents quantitative information about the inputs and valuation methodologies used for the Company s fair value measurements of contingent consideration classified as Level 3 as of September 30, 2018:

	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent Consideration	Probability weighted income approach	Milestone dates	2019-2026
		Discount rate Probability of occurrence	3.9% to 9.3% 23% - 86%

#### 4. Prepaid Expenses and Other Current Assets

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

	September 30,				
	2018			December 31, 2017	
Prepaid manufacturing expense	\$	2,026,833	\$	1,551,597	
Prepaid insurance		335,583		218,750	
Other prepaid expenses		95,320		87,937	
Other current assets		20,015		108,973	
	\$	2,477,751	\$	1,967,257	

#### 5. Property and Equipment

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

Property and equipment consisted of the following:

	Se	eptember 30,			
	2018			December 31, 2017	
Furniture and fixtures	\$	55,883	\$	55,883	
Computers		33,096		41,333	
Lab equipment		1,189,752		645,433	
Total		1,278,731		742,649	
Accumulated depreciation		(615,666)		(455,758)	
Property and equipment, net	\$	663,065	\$	286,891	

Depreciation expense was \$171,235 and \$100,958 for the nine months ended September 30, 2018 and 2017, respectively.

# 6. Goodwill and In-Process R&D

Goodwill of \$2.2 million and in-process R&D of \$5.9 million were recorded in connection with the acquisition of Pelican, as described in Note 2. The carrying value of goodwill and in-process R&D has remained unchanged and no impairment was recognized as of September 30, 2018 and December 31, 2017.

# HEAT BIOLOGICS, INC.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

#### 7. Accrued Expenses and other payables

Accrued expenses and other payables consist of the following:

	September 30, 2018		December 31, 2017	
Accrued clinical trial and other expenses	\$	1,314,133	\$	1,504,240
Compensation and related benefits		86,038		542,434
Deferred rent		13,349		27,457
Patent fees		35,000		40,000
Other expenses		82,300		162,300
	\$	1,530,820	\$	2,276,431

# 8. Stock-Based Compensation

# Stock Options

The following is a summary of the stock option activity for the nine months ended September 30, 2018:

# Weighted

#### Average

#### Exercise

	Shares	Price
Outstanding, December 31, 2017	266,884	\$ 19.57
Granted	216,336	3.62
Forfeited	(17,814)	31.36

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Outstanding, September 30, 2018	465,406	\$	11.71

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2018 was \$2.67. The fair value of each stock option was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions for stock options granted during the nine months ended September 30, 2018:

Dividend yield	0.0%
Expected volatility	91.38%
Risk-free interest rate	2.44%
Expected lives (years)	6.1

The risk-free interest rate is based on U.S. Treasury interest rates at the time of the grant whose term is consistent with the expected life of the stock options. The Company used an average historical stock price volatility based on an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms, as the Company did not have sufficient trading history for its common stock. Expected term represents the period that the Company s stock option grants are expected to be outstanding. The Company elected to utilize the simplified method to estimate the expected term. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Expected dividend yield was considered to be 0% in the option pricing formula since the Company had not paid any dividends and had no plans to do so in the future. The forfeiture rate was considered to be none as the options vest on a monthly basis.

## HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The Company recognized \$112,730 and \$122,657 in stock-based option compensation expense for the three months ended September 30, 2018 and 2017, respectively and \$354,877 and \$367,800 in stock-based option compensation expense for the nine months ended September 30, 2018 and 2017, respectively. The following table summarizes information about stock options outstanding at September 30, 2018:

	Options Outstanding Weighted			Options Vested and Exercisable Weighted			
	Average			Average			
	Remaining	Weighted		Remaining	Weighted		
	Contractual	Average	Balance	Contractual	Average		
	Life	Exercise	as of	Life	Exercise		
<b>9/30/2018</b> 465,406	( <b>Years</b> ) 8.4	<b>Price</b> \$11.71	<b>9/30/2018</b> 180,274	(Years) 7.3	<b>Price</b> \$22.08		

As of September 30, 2018, the unrecognized stock-based compensation expense related to unvested stock options was \$1,475,129, which is expected to be recognized over a weighted average period of approximately 16 months.

#### **Restricted Stock**

The Company recognized \$27,084 and \$16,314 in stock-based compensation expense for employees related to restricted stock awards during the three months ended September 30, 2018 and 2017, respectively, and \$292,312 and \$152,521 in stock-based compensation expense for employees related to restricted stock awards during the nine months ended September 30, 2018 and 2017, respectively. The Company recognized \$800 and \$5,000 in share-based compensation expense related to issuance of shares of restricted stock to non-employees (i.e., consultants) in exchange for services during the three months ended September 30, 2018 and 2017, respectively and \$5,557 and \$26,000 in share-based compensation expense related to issuance of shares of restricted stock to non-employees (i.e., consultants) in exchange for services during the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, there were 61,144 restricted stock awards granted to employees and non-employees, all of which were unvested.

Total stock-based compensation expense, including restricted stock and stock options was \$652,746 and \$546,321 for the nine months ended September 30, 2018 and 2017, respectively.

# 9. Financing

# **Public Offering**

On May 7, 2018, the Company closed an underwritten public offering (the Offering ) in which it issued and sold (i) 4,875,000 shares of common stock together with a number of common warrants to purchase 2,437,500 shares of its common stock, and (ii) 9,500,000 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock, together with a number of common warrants to purchase 4,750,000 shares of its common stock. The public offering price was \$1.44 per share of common stock, \$1.43 per pre-funded warrant and \$0.01 per common warrant. The net proceeds to the Company were approximately \$18.8 million, net of underwriting discounts and commissions and other estimated offering expenses. The common stock warrants expire five years after date of issuance and have an exercise price of \$1.584 per share. As of September 30, 2018, 3,054,667 common stock warrants have been exercised for an additional \$4.8 million of proceeds to the Company and all pre-funded warrants have been exercised. In connection with the offering the Company entered into an underwriting agreement (the Underwriting Agreement contained customary representations, warranties, and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended (the Securities Act ), other obligations of the parties and termination provisions.

## HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

#### At the Market Offering

On January 18, 2018, the Company entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC, ( HCW ) as sales agent, pursuant to which the Company may sell from time to time, at its option, shares of its common stock, for the sale of up to \$3,658,000 of shares of the Company s common stock and on March 15, 2018 filed with the SEC a prospectus supplement for an additional aggregate offering of up to \$1,300,000 shares of Common Stock. Sales of shares of Common Stock have been made pursuant to the Company s shelf registration statement on Form S-3 (File No. 333-221201) filed with the U.S. Securities and Exchange Commission ( SEC ), dated November 13, 2017. As of September 30, 2018, the Company sold an aggregate of 1,545,449 shares of common stock under the HCW Sales Agreement resulting in net proceeds of approximately \$3.7 million.

#### **Common Stock Warrants**

In connection with the May 7, 2018 public offering, the Company issued 9,500,000 pre-funded warrants and 7,187,500 common stock warrants each of which are exercisable for one share of common stock. The pre-funded warrants had an exercise price of \$0.01 per share and as of September 30, 2018 all pre-funded warrants have been exercised. The common stock warrants have an exercise price of \$1.584 per share and expire five years from the issuance date. As of September 30, 2018, 3,054,667 common stock warrants have been exercised. The warrants have been accounted for as equity instruments. The fair value of the common stock warrants of approximately \$7.8 million at the date of issuance was estimated using the Black-Scholes Merton model which used the following inputs: term of 5 years, risk free rate of 2.78%, 0% dividend yield, volatility of 124.14%, and share price of \$1.30 per share based on the trading price of the Company s common stock.

In connection with the March 23, 2017 public offering, the Company issued warrants to purchase 682,500 shares of common stock with an exercise price of \$10.00 per share that expire five years from the issuance date. In connection with the Company s July 23, 2013 initial public offering, the Company issued warrants to the underwriters for 12,500 shares of common stock issuable at \$125.00 per share which expired July 22, 2018. On March 10, 2011, the Company issued warrants to purchase shares of common stock to third parties in consideration for a private equity placement transaction of which 1,738 warrants remain outstanding. The warrants have an exercise price of \$4.80 per share and expire ten years from the issuance date.

During the nine months ended September 30, 2018, 3,054,667 common stock warrants have been exercised and 12,500 common stock warrants have expired. No warrants were exercised during the same period in 2017. As of September 30, 2018 the Company has outstanding warrants to purchase 4,132,833 shares of common stock issuable at \$1.584 per share, 296,159 shares of common stock issuable at \$10.00 per share; and warrants to purchase 1,738 shares of common stock issuable at \$4.80 per share. These warrants do not meet the criteria required to be classified as liability awards and therefore are treated as equity awards.

## **10. Grant and Licensing Revenues**

In June 2016, Pelican entered into a Cancer Research Grant Contract (Grant Contract) with CPRIT, under which CPRIT awarded a grant not to exceed \$15.2 million for use in developing cancer treatments by targeting a novel T-cell costimulatory receptor (namely, TNFRSF25). The Grant Contract covers a period from June 1, 2016 through October 31, 2019.

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

The Company recognized grant revenue of approximately \$1.8 million and \$3.7 million during the three and nine months ended September 30, 2018 for qualified expenditures under the grant. The Company recognized grant revenue of approximately \$0.5 million and \$0.9 million during the three and nine months ended September 30, 2017, including an additional \$0.02 million of research funding revenue for research and development services provided to Shattuck Labs, Inc. which research funding agreement terminated January 31, 2017.

## **HEAT BIOLOGICS, INC.**

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

As of September 30, 2018, the Company had deferred revenue of \$3.1 million for proceeds received from the CPRIT grant, but for which the costs had not been incurred or the conditions of the award had not been met. The Company had deferred revenue, net of current portion of \$0.2 million grant funds received from an economic development grant agreement with the City of San Antonio (Economic Development Grant), for the purpose of defraying costs toward the purchase of laboratory equipment.

#### 11. Net Loss Per Share

Basic and diluted net loss per common share is calculated by dividing net loss applicable to Heat Biologics, Inc. by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. The Company s potentially dilutive shares, which include outstanding stock options and warrants, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. The following table reconciles net loss to net loss attributable to Heat Biologics, Inc.:

		<b>Three Months Ended</b>			Nine Months Ended		
	September 30,				September 30,		
		2018		2017	2018	2017	
Net loss Net loss: Non-controlling	\$	(3,923,586)	\$	(2,504,178) \$	(11,463,927)	\$ (9,053,987) )	
interest Net loss attributable to Heat Biologics,		(265,024)		(203,371)	(668,219)	(344,328	
Inc.	\$	(3,658,562)	\$	(2,300,807) \$	(10,795,708)	\$ (8,709,659	
Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc. basic and		23,143,952		3,578,661	14,359,429	3,269,536	

diluted				
Net loss per share				
attributable to				
Heat Biologics,				
Inc. basic and				
diluted	\$ (0.16)	\$ (0.64) \$	(0. 75)	\$ (2.66)

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

#### For the Nine months Ended

	September 30,		
	2018	2017	
Outstanding stock options	465,406	267,355	
Outstanding restricted stock units	61,144	29,138	
Outstanding common stock warrants	4,430,730	310,397	

#### 12. Income Tax

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases, operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. As of September 30, 2018, \$0.7 million of the deferred tax asset arising from the generation of 2018 net operating losses has been utilized to offset a portion of the previously recorded deferred tax liability associated with indefinite lived R&D in process costs. Specifically, the current year net operating losses gave rise to an indefinite-lived deferred tax asset which provided sufficient support to offset a portion of the Company s indefinite-lived deferred tax liability.

In accordance with FASB ASC 740, Accounting for Income Taxes, the Company reflects in the accompanying unaudited condensed consolidated financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered more-likely-than-not that the position taken will be sustained by a taxing authority. As of September 30, 2018, and December 31, 2017, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company s effective income tax rate associated with these items. The Company s policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of operations and comprehensive loss. As of September 30, 2018, and December 31, 2017, the Company had no such accruals.

## HEAT BIOLOGICS, INC.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

#### **13. Subsequent Events**

On October 2, 2018, the Company held its 2018 Annual Meeting of Stockholders (the Annual Meeting ). At the Annual Meeting, the Company s stockholders (i) elected the following four individuals as directors: Jeffrey Wolf, John Monahan, Ph.D., Edward B. Smith, III, and John Prendergast, Ph.D.; (ii) ratified and approved the appointment of BDO USA, LLP as the Company s independent registered public accounting firm for the year ending December 31, 2018; and (iii) approved and adopted the Company s 2018 Stock Incentive Plan, which allows the Company to grant up to 4,000,000 awards under the 2018 Stock Incentive Plan.

Effective October 31, 2018, the Company entered into an exchange agreement with the University of Miami pursuant to which the Company agreed to issue 35,000 shares of its common stock to the University of Miami in exchange for the return to the Company by the University of Miami of certain shares of capital stock it held in the Company s subsidiaries, Heat Biologics I, Inc. and Pelican Therapeutics, Inc.

# ITEM 2.

# MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included in this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed below and elsewhere in this Quarterly Report. This discussion should be read in conjunction with the accompanying unaudited consolidated financial statements and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission on March 2, 2018 (the 2017 Annual Report ). This discussion may contain forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements.

## **OVERVIEW**

We are a biopharmaceutical company developing immunotherapies with the goal of activating a patient s immune system against cancer through T-cell activation. Our T-cell Activation Platform (TCAP), includes two TCAPs, plus a novel T cell co-stimulator program, PTX-35. These programs are designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. We 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 (Opdiv®). Our other programs are in pre-clinical development with two IND filings anticipated in the next few months.

Our T-cell Activation Platform (TCAP), includes two TCAPs, Immune Pan-antigen Cytotoxic Therapy (*ImPACT*<sup>®</sup>) and Combination Pan-antigen Cytotoxic Therapy (*ComPACT*) which are designed to activate killer T-cells to destroy a patient s cancer and stimulate T-cells prime immune recognition of tumors that turn COLD Tumors HOT. By turning COLD tumors HOT, we believe our platform will become an essential component of the immuno-oncology cocktail to enhance the effectiveness of checkpoint inhibitors and other cancer therapies, thereby improving outcomes for those patients least likely to respond to checkpoint inhibitors alone.

We believe the advantage of our approach is that our biologic agents have demonstrated the capability to bind a broad swath of tumor antigens to be recognized by the immune system. We combine broad antigen targeting of known and unknown tumor associated antigens complexed with a powerful, naturally occurring immune adjuvant, gp96. The treatment primes immune recognition and is designed to trigger the body to stimulate the immune system to seek and destroy the cancer cells. These agents can be administered with a variety of immuno-modulators to enhance a patient s

immune response through T-cell activation.

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

Heat s ImPAC platform is a cell-based, T-cell-stimulating platform that functions as an immune activator to stimulate T-cells.  $ImPACT^{(0)}$  reprograms a live, genetically modified cancer cell line to continually secrete the heat-shock protein, gp96. Once the cell line is injected into the body along with a checkpoint inhibitor, they are bound to the cell s own mutated antigens bound to gp96.

Heat Biologics has harnessed the unique, dual functionality of the heat shock protein, gp96, to develop its innovative immunotherapy platform. gp96, is present in all human cells, and when released, it activates the T-cell arm of the immune system against unrecognized, foreign antigens.

As a molecular chaperone, gp96 is typically found within the cell s endoplasmic reticulum and facilitates the folding of newly synthesized proteins so they can properly perform their various tasks. But when a cell abnormally dies through necrosis or infection, gp96 is naturally released into the surrounding tissues, causing damage to other cells. At this moment, gp96 becomes a molecular warning signal to the innate immune system. This part of the immune system is designed to activate CD8+ T cells exclusively.

gp96 serves as a potent adjuvant, or immune stimulator, via Toll-Like Receptor 4/2 (TLR4 and TLR2) which normally serves as an alert to harmful pathogens. It is among the most powerful adjuvants found in the body and uniquely shows exclusive specificity to CD8+ killer T-cells. Thus, gp96 plays a critical role in the mechanism of Heat s immuno-therapies and T-cell activating platforms.

Through proprietary modifications to gp96, Heat s ImPACP technology reprograms live cancer cells to continually secrete their own mutated cancer antigens bound to the gp96 chaperone, thus stimulating the immune system, alerting it to the presence of a tumor, with the goal of activating a T-cell response against those tumors associated. In this way,  $ImPACT^{(B)}$  therapies mimic necrotic cell death and activate a powerful, tumor antigen-specific T-cell immune response to attach the patient s cancer cells.

*ComPACT*, our second TCAP, is a dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. *ComPACT* helps unlock the body s natural defenses and builds upon *ImPAC*? by providing co-stimulation to enhance T-cell activation and expansion. It has the potential to simplify combination immunotherapy development for oncology patients, as it is designed to deliver the gp96 heat shock protein and a T-cell co-stimulatory fusion protein (OX40L) into a single compound, without the need for multiple, independent biologic products. The potential advantages of *ComPACT* include: (a) enhanced activation of antigen-specific CD8+ T-cells compared to; (b) serving as a booster to expand the number of antigen-specific T cells compared to OX40 alone; (c) stimulation of T-cell memory function to remain effective in the body after treatment, even if the cancer comes back; (d) demonstration of less toxicity, as the unique identifier and co-stimulator are supplied at the same time, driving targeted immunity towards the tumor rather than throughout the body; and (e) potential paradigm shift that is designed to simplify combination cancer immunotherapy and has implications for local T cell co-stimulation versus co-stimulation with conventional monoclonal antibodies (mAbs).

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

When combined with immunotherapies, including the *ImPACT*<sup>®</sup> and *ComPACT* platform technologies, PTX-35 has been shown to enhance antigen specific T-cell activation to eliminate tumor cells. Pelican is also developing other biologics that target TNFRSF25 for various immunotherapy approaches, including PTX-15, a human TL1A-lg fusion protein designed as a shorter half-life agonist of TNFRSF25.

Currently we are enrolling patients in our HS-110 combination immunotherapy trial, preparing for IND submission of HS-130 (*ComPACT*), advancing pre-clinical development of Pelican assets in anticipation of an IND submission expected in Q1 2019, providing general and administrative support for these operations and protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any significant revenue since our inception and no revenue from product sales. We expect to continue to incur significant expenses and to incur increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

complete the ongoing clinical trials of our product candidates;

maintain, expand and protect our intellectual property portfolio;

seek to obtain regulatory approvals for our product candidates;

continue our research and development efforts;

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add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and

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operate as a public company.

# **Recent Developments**

On August 14, 2018, we reported that we remain on track to report additional interim Phase 2 data in Q4 2018 and complete enrollment in Q2 2019 for our Phase 2 trial investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced NSCLC. We have completed a Pre-IND Type B meeting with FDA for our next generation *ComPACT* product and plan to file our Phase 1 Investigational New Drug (IND) in Q1 2019, as well as a second IND application to initiate a Phase 1 clinical trial for PTX-35 in Q1 2019.

On October 4, 2018, we provided a progress update on our novel PTX-35 co-stimulatory antibody, including:

# (a)

completed cell line development and creation of validated master cell bank for cGMP manufacturing;

(b)

established CMC path for the production of GMP clinical material and non-clinical preliminary pharmacology / non-GLP toxicology studies;

(c)

reported on preliminary non-GLP pharmacology, which demonstrated positive results, including efficient binding and activation on cells expressing the TNFRSF25 receptor, as well as increased expansion of T-cells in-vivo;

(d)

reported on 2-week IND enabling dose range finding toxicology studies in primates receiving two doses, which showed no signs or signals of clinical toxicity across wide dose range; and

(e)

reported on ongoing pre-IND discussions with FDA and expectation to submit IND in Q1, 2019.

# CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

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

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

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

Revenue;

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Deferred revenue;

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In-process R&D;

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Income tax;

Contingent consideration;

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Stock-based compensation; and

Research and development costs, including clinical and regulatory cost.

## **RESULTS OF OPERATIONS**

#### Comparison of the Three months ended September 30, 2018 and 2017

Revenues

For the three months ended September 30, 2018 and 2017, we recognized \$1.8 million and \$0.5 million of grant revenue for qualified expenditures under the CPRIT grant. As of September 30, 2018, we had deferred revenue of \$3.3 million for proceeds received but for which the costs had not been incurred or the conditions of the award had not been met. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.

Research and development expense.

Research and development expenses increased approximately 144.4% to \$4.4 million for the three months ended September 30, 2018 compared to \$1.8 million for the three months ended September 30, 2017. The components of R&D expense are as follows, in millions:

	Three months Ended, September 30,			
		2018	2	017
Programs				
HS-110	\$	0.7	\$	0.6
HS-410		0.1		0.1
HS-130		0.2		0.0
PTX 35/other biologics against TNFRSF25		2.5		0.0
Other programs		0.1		0.2
Unallocated research and development expenses		0.8		0.9
	\$	4.4	\$	1.8

HS-110 expense increased \$0.1 million, as we increase patient enrollment in the phase 2 portion of the clinical trial.

HS-410 long-term follow up completed and program in close-out.

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HS-130 expense increased by \$0.2 million as we continue our development of clinical trial material for this program.

PTX expense for the three months ended September 30, 2018 was \$2.5 million as we continue pre-clinical development of PTX-35 and other biologics against TNFRSF25 for testing in patients.

Other programs include preclinical costs associated with our Zika program, T-cell costimulatory programs, and laboratory supplies.

*General and administrative expense.* General and administrative expense increased approximately 33.3% to \$1.6 million for the three months ended September 30, 2018 compared to \$1.2 million for the three months ended September 30, 2017. The \$0.4 million increase consists of professional services/consulting fees associated with our 2018 Annual Meeting of Shareholders as well as an increase in investor relations and new business development fees during the three months ended September 30, 2018.

*Change in fair value of contingent consideration.* We reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. The change in the fair value of contingent consideration was \$114,838 for the three months ended September 30, 2018. There was no change in the fair value for the three months ended September 30, 2017.

*Interest income*. Interest income was \$83,509 for the three months ended September 30, 2018 compared to \$5,629 for the three months ended September 30, 2017. The increase of \$77,880 is due to the increased cash equivalent balance as well as investment in various short-term financial instruments that generated interest income during the three months ended September 30, 2018.

*Other income*. Other income was \$31,704 for the quarter ended September 30, 2018 compared to \$31,768 for the quarter ended September 30, 2017. For the three months ended September 30, 2018 other income is primarily related to the annual 2017 R&D Australian tax credit received during the quarter offset by foreign currency loss. In 2017, other income is primarily related to the reimbursement of taxes expensed during the previous quarter offset by foreign currency gains.

*Income Tax Benefit.* Income tax benefit for the three months ended September 30, 2018 consists of \$0.2 million federal tax benefit due to the application of the tax benefit calculated on indefinite-lived 2018 NOLs.

*Net loss attributable to Heat Biologics, Inc.* We had a net loss attributable to Heat Biologics, Inc. of \$3.7 million, or (\$0.16) per basic and diluted share for the three months ended September 30, 2018 compared to a net loss of \$2.3 million, or (\$0.64) per basic and diluted share for the three months ended September 30, 2017.

## Comparison of the Nine months ended September 30, 2018 and 2017

Revenues

For the nine months ended September 30, 2018, we recognized \$3.7 million of grant revenue for qualified expenditures under the CPRIT grant. For the nine months ended September 30, 2017, we recognized \$0.9 million of grant and licensing revenue, primarily consisting of grant revenue for qualified expenditures under the CPRIT grant. Included in 2017 revenue, is \$0.02 million of research funding revenue for research and development services, provided to Shattuck Labs, Inc. which research funding agreement terminated January 31, 2017. As of September 30, 2018, we had deferred revenue of \$3.3 million for proceeds received but for which the costs had not been incurred or the conditions of the award had not been met. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.

Research and development expense.

Research and development expenses increased approximately 86.2% to \$10.8 million for the nine months ended September 30, 2018 compared to \$5.8 million for the nine months ended September 30, 2017. The components of R&D expense are as follows, in millions:

	Nine months Ended, September 30,			
	20	018	2	017
Programs				
HS-110	\$	2.5	\$	2.0
HS-410		0.2		0.6
HS-130		0.7		0.0

PTX 35/other biologics against TNFRSF25	4.7	0.0
Other programs	0.3	0.5
Unallocated research and development expenses	2.4	2.7
	\$ 10.8	\$ 5.8

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HS-110 expense increased \$0.5 million, as we increase patient enrollment in the phase 2 portion of the clinical trial.

HS-410 expense decreased \$0.4 million due to completion of long-term follow up and program close-out.

HS -130 expense increased by \$0.7 million as we continue our development clinical trial material for this program.

PTX expense for the nine months ended September 30, 2018 was \$4.7 million as we continue pre-clinical development of PTX-35 and other biologics against TNFRSF25 for testing in patients.

Other programs include preclinical costs associated with our Zika program, T-cell costimulatory programs, and laboratory supplies.

*General and administrative expense*. General and administrative expense increased approximately 9.3% to \$4.7 million for the nine months ended September 30, 2018 compared to \$4.3 million for the nine months ended September 30, 2017. The variance of \$0.4 million is due to an increase in operations costs, professional services and consulting fees, and personnel costs as we establish our Texas operations associated with our Pelican subsidiary. Included in General and administrative expense for the nine months ended September 30, 2017 were the acquisition costs for Pelican.

*Change in fair value of contingent consideration.* We reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. The change in the fair value of contingent consideration was \$665,936 for the nine months ended September 30, 2018. There was no change in the fair value for the nine months ended September 30, 2017.

*Interest income*. Interest income was \$131,306 for the nine months ended September 30, 2018 compared to \$17,316 for the nine months ended September 30, 2017. The increase of \$113,990 is due to the increased cash equivalent balance as well as investment in various short-term financial instruments that generated interest income during the nine months ended September 30, 2018.

*Other income*. Other income increased to \$153,500 for the nine months ended September 30, 2018 compared to \$109,211 for the nine months ended September 30, 2017. In 2018, other income is primarily related to the release of escrow funds to us for payment of liabilities related to the Pelican acquisition. In 2017, other income was primarily related to foreign currency gains on several transactions in Australia.

*Income Tax Benefit.* Income tax benefit for the nine months ended September 30, 2018 consists of \$0.7 million federal tax benefit due to application of the tax benefit calculated on indefinite-lived 2018 NOLs.

*Net loss attributable to Heat Biologics, Inc.* We had a net loss attributable to Heat Biologics, Inc. of \$10.8 million, or (\$0.75) per basic and diluted share the nine months ended September 30, 2018 compared to a net loss of \$8.7 million, or (\$2.66) per basic and diluted share for the nine months ended September 30, 2017.

#### Balance Sheet at September 30, 2018 and December 31, 2017

*Prepaid Expenses and Other Current Assets.* Prepaid expenses and other current assets was approximately \$2.5 million as of September 30, 2018 and \$2.0 million as of December 31, 2017. The \$0.5 million increase was primarily attributable to the amount paid in advance for cGMP production for PTX-35 antibody and other TNFRSF25 targeted biologics (including PTX-15, the fusion protein).

*In-Process R&D and Goodwill.* As of September 30, 2018 and December 31, 2017, we had in-process R&D of \$5.9 million and goodwill of \$2.2 million from our acquisition of Pelican. The fair value of these assets did not change during the nine months ended September 30, 2018.

*Accounts Payable.* Accounts payable was approximately \$1.0 million as of September 30, 2018 and December 31, 2017. Accounts payables primarily consist of payables for CMC as well as investigator site payments for our clinical trials.

*Deferred Revenue.* We had deferred revenue of \$3.3 million and \$7.0 million as of September 30, 2018 and December 31, 2017, respectively. This deferred revenue primarily represents proceeds received for the CPRIT grant but for which the costs had not been incurred or the conditions of the award had not been met and \$0.2 million related to an economic development grant received from San Antonio for the purchase of lab equipment.

*Accrued Expenses and Other Liabilities.* Accrued expenses and other liabilities were approximately \$1.5 million as of September 30, 2018 compared to approximately \$2.3 million as of December 31, 2017. The decrease of approximately \$0.8 million was related to 2017 employee bonuses which were accrued at December 31, 2017 but subsequently paid in January 2018.

*Deferred Tax Liability*. Deferred tax liability was approximately \$0.6 million as of September 30, 2018 compared to approximately \$1.3 million as of December 31, 2017. The decrease of approximately \$0.7 million was related to application of the tax benefit calculated on indefinite-lived 2018 NOLs.

*Contingent Consideration.* As of September 30, 2018, we had contingent consideration of \$3.3 million related to our acquisition of Pelican. This amount represents the fair value of future milestone payments to Pelican shareholders which were discounted in accordance with ASC 805. We perform an analysis on a quarterly basis and as of September 30, 2018, we determined the change in the estimated fair value of the contingent consideration \$0.7 million for the nine months ended September 30, 2018.

# LIQUIDITY AND CAPITAL RESOURCES

#### **Sources of Liquidity**

We commenced active operations in June 2008. Initially, we financed our operations from the private placement of our preferred stock, common stock and debt. More recently, we have primarily financed our operations with net proceeds from the public offering of our common stock and to a lesser extent, the proceeds from the exercise of warrants. During May 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately \$18.8 million and after the closing of the offering, an additional \$4.8 million from the exercise of 3,054,667 warrants issued in this offering. In addition, from August 2016 through July 2017 we received an aggregate of \$9.3 million of net proceeds through our At Market Issuance Sales Agreement (the FBR Sales Agreement ) with B. Riley FBR, Inc. formerly known as FBR Capital Markets & Co. On January 18, 2018, we entered into the H.C. Wainwright Sales Agreement that replaced the FBR Sales Agreement. To date, we received net proceeds of approximately \$3.7 million from the sale of shares of our common stock through the H.C. Wainwright Sales Agreement. As of September 30, 2018, we have received \$8.3 million in grant funding from the CPRIT Grant through Pelican. As of September 30, 2018, we had an accumulated deficit of \$79.6 million. We had net losses of \$11.5 million and \$9.1 million for the nine months ended September 30, 2018 and 2017, respectively.

We expect to incur significant expenses and continued losses from operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and advance our clinical trials of, and seek marketing approval for, our product candidates and as we continue to fund the Pelican matching funds required in order to access the CPRIT Grant. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. To meet our capital needs, we intend to continue to consider multiple alternatives, including, but not limited to, additional equity financings such as sales of our common stock under the H.C. Wainwright Sales Agreement if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our product candidates. We will need to generate significant revenues to achieve profitability, and we may never do so. As of September 30, 2018, we had approximately \$21.0 million in cash and cash equivalents.

Our cash and cash equivalents are currently held in an interest-bearing checking account and money market accounts.

# **Cash Flows**

*Operating activities.* The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. The increase in cash used in operating activities for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 is primarily due to an increase in pre-clinical activities associated with our PTX programs.

*Investing activities.* The use of cash in all periods was related to the purchase of property and equipment. The increase is due to the purchase of lab equipment as we establish our San Antonio facilities as required per the CPRIT Grant.

*Financing activities.* Cash provided by financing activities during the nine months ended September 30, 2018 was primarily from the May 7, 2018 public offering which generated net proceeds of approximately \$18.8 million and an additional \$4.8 million from the exercise of warrants, as well as approximately \$3.7 million net proceeds from the HCW sales agreement.

Cash provided by financing activities during the nine months ended September 30, 2017 was from the March 2017 public offering which generated net proceeds of approximately \$4.1 million, as well as \$2.3 million net proceeds from the FBR sales agreement.

#### **Funding Requirements**

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash needs for the next twelve months. However, we expect to incur additional expenses as we continue our research and development programs. To meet our future financing needs, we intend to continue to consider multiple alternatives, including, but not limited to, additional equity financings, debt financings, partnerships, collaborations and other funding transactions. We are continually evaluating and monitoring our cash requirements and look to implement cost savings measures when necessary.

# **OFF-BALANCE SHEET ARRANGEMENTS**

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

#### **ITEM 3.**

# QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable to smaller reporting companies.

ITEM 4.

#### **CONTROLS AND PROCEDURES.**

## **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Vice President of Finance, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We have adopted and maintain disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. The Company s disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure

controls and procedures as of September 30, 2018 our Chief Executive Officer and Vice President of Finance concluded that, as of such a date, our disclosure controls and procedures were effective at the reasonable assurance level.

## **Changes in Internal Control over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) occurred during the quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# PART II OTHER INFORMATION

#### ITEM 1.

## LEGAL PROCEEDINGS.

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

## ITEM 1A.

# **RISK FACTORS.**

The following information and updates should be read in conjunction with the information disclosed in Part 1, Item 1A, Risk Factors, contained in our 2017 Annual Report. Except as disclosed below, there have been no material changes from the risk factors and uncertainties disclosed in our 2017 Annual Report.

# 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 nine months ended September 30, 2018 and 2017, we incurred a net loss of approximately \$11.5 million and \$9.1 million, respectively. We have an accumulated deficit of approximately \$79.6 million through September 30, 2018. For the years ended December 31, 2017 and 2016, we incurred a net loss of approximately \$12.4 million and \$13.0 million, respectively. We had an accumulated deficit of approximately \$68.8 million through December 31, 2017. 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.

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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 nine months ended September 30, 2018, our operating activities used net cash of approximately \$15.7 million and as of September 30, 2018, our cash and cash equivalents were approximately \$21.0 million. 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. We have experienced significant losses since inception and have a significant accumulated deficit. As of September 30, 2018, our accumulated deficit totaled approximately \$79.6 million and as of December 31, 2017, our cash and cash equivalents were approximately \$0.2018, our accumulated deficit totaled approximately \$79.6 million and as of December 31, 2017, our accumulated deficit totaled approximately \$68.8 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. We do not expect to derive revenue from any significant source in the near future until we or our potential partners successfully commercialize our products. Despite cost-saving measures that we implemented, we expect our expenses to increase if and when we initiate and conduct Phase 3 and other clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future, we will have to fund all of our

operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees and grants.

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

We will need to raise additional capital to fund our future operations and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. To meet our future financing needs, we intend to consider 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, 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 have never paid cash dividends and have no plans to pay 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.

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.

# ITEM 2.

# UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None that were not previously disclosed in our Current Reports on Form 8-K.

# ITEM 3.

# DEFAULTS UPON SENIOR SECURITIES.

Not Applicable.

ITEM 4.

# MINE SAFETY DISCLOSURES.

Not Applicable.

# ITEM 5.

# **OTHER INFORMATION.**

Effective October 31, 2018, we entered into an exchange agreement with the University of Miami pursuant to which we agreed to issue 35,000 shares of our common stock to the University of Miami in exchange for the return to us by the University of Miami of certain shares of capital stock it held in our subsidiaries, Heat Biologics I, Inc. and Pelican Therapeutics, Inc.

ITEM 6.

EXHIBITS.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

# SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

# HEAT BIOLOGICS, INC.

Date: November 14, 2018	By:	/s/ Jeffrey A. Wolf Jeffrey A. Wolf Chairman and Chief Executive Officer (Principal executive officer)
Date: November 14, 2018	By:	/s/ Ann A. Rosar Ann A. Rosar Vice President of Finance (Principal financial and accounting officer)

# EXHIBIT INDEX

Exhibit No.	Description
3.1	Third Amended and Restated Certificate of Incorporation (previously filed as an exhibit to the
	Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013
	<u>(File No. 333-188365))</u>
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (previously
	filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange
	Commission on May 30, 2013 (File No. 333-188365))
3.4	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (previously
	filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission
	<u>on July 17, 2017 (File No. 001-35994))</u>
3.5	Amended and Restated Bylaws of Heat Biologics, Inc. (incorporated by reference to Registrant s
	Current Report on Form 8-K filed with the Securities and Exchange Commission dated July 20, 2018
	<u>(File No. 001-35994).</u>
4.1	Heat Biologics, Inc. 2018 Stock Incentive Plan (incorporated by reference to Registrant s Registration
	Statement on Form S-8 (File No. 333-227699) filed with the Securities and Exchange Commission on
	<u>October 4, 2018).</u>
4.2	Specimen Common Stock Certificate (previously filed as an exhibit to the Registration Statement on
	Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities
	Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Vice President of Finance pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities
	Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to
	Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Vice President of Finance pursuant to 18 U.S.C. Section 1350, as adopted pursuant to
	Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\*

Filed herewith.