UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

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	**26-2844103**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
627 Davis Drive, Suite 400 Morrisville, NC	**27560**
(Address of Principal Executive Offices)	*(Zip Code)*

(919) 240-7133
(Registrant's Telephone Number, including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	HTBX	Nasdaq Capital Market

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 ☑ No ☐

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

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

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

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

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

As of November 13, 2019, there were34,140,652 shares of Common Stock, $0.0002 par value per share, outstanding.

HEAT BIOLOGICS, INC.

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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," "would," "could," "should," "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, 2018 filed with the SEC on March 28, 2019 and Amendment No. 1 thereto filed with the SEC on April 24, 2019. 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.

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	September 30, 2019 (unaudited)	December 31, 2018
Current Assets		
Cash and cash equivalents	$ 9,334,421	$ 22,154,251
Short-term investments	5,683,446	5,570,027
Accounts receivable	37,300	28,538
Prepaid expenses and other current assets	734,788	961,317
Total Current Assets	15,789,955	28,714,133
Property and Equipment, net	609,916	643,146
Other Assets		
In-process R&D	5,866,000	5,866,000
Goodwill	1,452,338	2,189,338
Right-of-use asset	347,153	—
Deposits	386,284	351,220
Total Other Assets	8,051,775	8,406,558
Total Assets	$ 24,451,646	$ 37,763,837
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 1,944,333	$ 974,619
Deferred revenue	—	1,032,539
Contingent consideration, current portion	1,477,000	1,187,000
Operating lease liability, current portion	91,068	—
Accrued expenses and other liabilities	1,281,911	1,678,051
Total Current Liabilities	4,794,312	4,872,209
Long Term Liabilities		
Contingent consideration	2,356,515	1,918,225
Deferred tax liability	361,911	316,733
Deferred revenue, net of current portion	200,000	200,000
Operating lease liability, net of current portion	259,222	—
Other long-term liabilities	306,235	213,724
Total Liabilities	8,278,195	7,520,891
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $.0002 par value; 100,000,000 shares authorized, 33,334,124 and 32,492,144 shares issued and outstanding at September 30, 2019 (unaudited) and December 31, 2018, respectively	6,822	6,499
Additional paid-in capital	117,836,082	114,883,135
Accumulated deficit	(101,261,124)	(84,580,180)
Accumulated other comprehensive loss	52,230	(19,904)
Total Stockholders' Equity– Heat Biologics, Inc.	16,634,010	30,289,550
Non-Controlling Interest	(460,559)	(46,604)
Total Stockholders' Equity	16,173,451	30,242,946
Total Liabilities and Stockholders' Equity	$ 24,451,646	$ 37,763,837

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended, September 30,		Nine months Ended, September 30,	
	2019	2018	2019	2018
Revenue:				
Grant and licensing revenue	$ 6,439	$ 1,840,009	$ 1,049,988	$ 3,735,713
Operating expenses:				
Research and development	3,129,356	4,403,759	9,725,744	10,756,485
General and administrative	1,993,136	1,585,600	7,201,196	4,727,105
Goodwill impairment loss	737,000	—	737,000	—
Change in fair value of contingent consideration	502,000	114,838	728,290	665,936
Total operating expenses	6,361,492	6,104,197	18,392,230	16,149,526
Loss from operations	(6,355,053)	(4,264,188)	(17,342,242)	(12,413,813)
Interest income	97,415	83,509	373,060	131,306
Other (expense) income, net	(73,275)	31,704	(80,539)	153,500
Total non-operating income	24,140	115,213	292,521	284,806
Net loss before income taxes	(6,330,913)	(4,148,975)	(17,049,721)	(12,129,007)
Income tax benefit (expense)	—	225,389	(45,178)	665,080
Net loss	(6,330,913)	(3,923,586)	(17,094,899)	(11,463,927)
Net loss – non-controlling interest	(136,315)	(265,024)	(413,955)	(668,219)
Net loss attributable to Heat Biologics, Inc.	$ (6,194,598)	$ (3,658,562)	$ (16,680,944)	$ (10,795,708)
Net loss per share attributable to Heat Biologics, Inc.—basic and diluted	$ (0.18)	$ (0.16)	$ (0.50)	$ (0.75)
Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc.—basic and diluted	33,650,829	23,143,952	33,255,535	14,359,429
Other comprehensive loss:				
Net loss	$ (6,330,913)	$ (3,923,586)	$ (17,094,899)	$ (11,463,927)
Unrealized gain on foreign currency translation	63,711	39,377	72,134	110,648
Total other comprehensive loss	(6,267,202)	(3,884,209)	(17,022,765)	(11,353,279)
Comprehensive loss attributable to non-controlling interest	(136,315)	(265,024)	(413,955)	(668,219)
Comprehensive loss	$ (6,130,887)	$ (3,619,185)	$ (16,608,810)	$ (10,685,060)

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.
Consolidated Statements of Stockholders' Equity
(Unaudited)

	Three months ended September 30, 2019					
	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non-Controlling Interest	Total Stockholders' Equity
Balance at June 30, 2019	$ 6,822	$ 117,350,922	$ (95,066,526)	$ (11,481)	$ (324,244)	$ 21,955,493
Stock-based compensation	—	485,160	—	—	—	485,160
Other comprehensive loss	—	—	—	63,711	—	63,711
Net loss	—	—	(6,194,598)	—	(136,315)	(6,330,913)
Balance at September 30, 2019	**$ 6,822**	**$ 117,836,082**	**$ (101,261,124)**	**$ 52,230**	**$ (460,559)**	**$ 16,173,451**

	Nine months ended September 30, 2019					
	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2018	$ 6,499	$ 114,883,135	$ (84,580,180)	$ (19,904)	$ (46,604)	$ 30,242,946
Issuance of common stock, 16,300 shares	3	18,894	—	—	—	18,897
Exercise of stock options, 2,000 shares	—	2,120	—	—	—	2,120
Stock-based compensation	320	2,931,933	—	—	—	2,932,253
Other comprehensive loss	—	—	—	72,134	—	72,134
Net loss	—	—	(16,680,944)	—	(413,955)	(17,094,899)
Balance at September 30, 2019	**$ 6,822**	**$ 117,836,082`**	**$ (101,261,124)**	**$ 52,230**	**$ (460,559)**	**$ 16,173,451**

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.
Consolidated Statements of Stockholders' Equity
(Unaudited)

	Three months ended September 30, 2018					
	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non-Controlling Interest	Total Stockholders' Equity
Balance at June 30, 2018	$ 4,619	$ 103,953,477	$ (75,983,472)	$ (94,754)	$ (1,993,037)	$ 25,886,833
Issuance of common stock, 142,082 shares	28	292,997	—	—	—	293,025
Stock issuance costs	—	(8,776)	—	—	—	(8,776)
Stock-based compensation	—	140,626	—	—	—	140,626
Other comprehensive gain	—	—	—	39,377	—	39,377
Net loss	—	—	(3,658,562)	—	(265,024)	(3,923,586)
Balance at September 30, 2018	**$ 4,647**	**$ 104,378,324**	**$ (79,642,034)**	**$ (55,377)**	**$ (2,258,061)**	**$ 22,427,499**

	Nine months ended September 30, 2018					
	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2017	$ 840	$ 76,382,262	$ (68,846,326)	$ (166,025)	$ (1,589,842)	$ 5,780,909
Public offering, 14,375,000 shares, net of underwriter's discount	2,875	20,697,122	—	—	—	20,699,997
Exercise of warrants, 3,054,667 shares	611	4,837,982	—	—	—	4,838,593
Issuance of common stock, 1,545,449 shares	309	3,866,096	—	—	—	3,866,405
Stock issuance costs	—	(2,057,872)	—	—	—	(2,057,872)
Stock-based compensation	12	652,734	—	—	—	652,746
Other comprehensive gain	—	—	—	110,648	—	110,648
Net loss	—	—	(10,795,708)	—	(668,219)	(11,463,927)
Balance at September 30, 2018	**$ 4,647**	**$ 104,378,324**	**$ (79,642,034)**	**$ (55,377)**	**$ (2,258,061)**	**$ 22,427,499**

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS, INC.
Consolidated Statements of Cash Flows
(Unaudited)

	Nine months Ended September 30	
	2019	**2018**
Cash Flows from Operating Activities		
Net loss	$ (17,094,899)	$ (11,463,927)
Adjustments to reconcile net loss to net cash used in operating activities:		
Goodwill impairment loss	737,000	—
Depreciation	176,548	171,235
Stock-based compensation	2,932,253	652,746
Change in fair value of contingent consideration	728,290	665,936
Unrealized gain on investments	(5,589)	—
Increase (decrease) in cash arising from changes in assets and liabilities:		
Accounts receivable	(9,002)	(53,714)
Prepaid expenses and other current assets	225,245	(514,265)
Deferred financing costs	—	30,000
Accounts payable	971,062	(55,384)
Deferred revenue	(1,032,539)	(3,735,713)
Deferred tax liability	45,178	(665,080)
Accrued expenses and other liabilities	(316,317)	(743,519)
Other long-term liabilities	92,511	27,923
Deposits	(35,065)	(29,422)
Net Cash Used in Operating Activities	(12,585,324)	(15,713,184)
Cash Flows from Investing Activities		
Purchase of property and equipment	(143,318)	—
Purchase of short-term investments	(107,830)	(547,409)
Net Cash Used in Investing Activities	(251,148)	(547,409)
Cash Flows from Financing Activities		
Proceeds from public offering, net of underwriting discounts	—	20,699,997
Proceeds from the issuance of common stock, net of commissions	18,898	3,866,405
Proceeds from exercise of stock options	2,120	—
Proceeds from exercise of warrants	—	4,838,593
Stock issuance costs	—	(2,057,872)
Net Cash Provided by Financing Activities	21,018	27,347,123
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(4,376)	110,430
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	(12,819,830)	11,196,960
Cash, Cash Equivalents and Restricted Cash – Beginning of Period	22,154,251	9,765,359
Cash, Cash Equivalents and Restricted Cash – End of Period	$ 9,334,421	$ 20,962,319

See Notes to Consolidated Financial Statements

1. Basis of Presentation and Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial reporting. Certain information or footnote disclosures normally included in the annual 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, these financial statements include all normal and recurring adjustments necessary for the fair statement of the results for the interim periods presented. The results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2019.

The consolidated financial statements as of and for the three and nine months ended September 30, 2019 and 2018 are unaudited. The balance sheet as of December 31, 2018 is derived from the audited consolidated financial statements as of that date. These 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, 2018 filed with the SEC on March 28, 2019 and Amendment No. 1 thereto filed with the SEC on April 24, 2019 (the "2018 Annual Report").

The consolidated financial statements as of and for the three and nine months ended September 30, 2019 and 2018 include the accounts of Heat Biologics, Inc. ("the Company"), and its subsidiaries, Pelican Therapeutics, Inc. ("Pelican"), Heat Biologics I, Inc. ("Heat I"), Heat Biologics III, Inc. ("Heat III"), Heat Biologics IV, Inc. ("Heat IV"), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd., Zolovax, Inc., Delphi Therapeutics, Inc. and Scorpion Biosciences, Inc.. The functional currency of the entities located outside the United States of America (the foreign entities) is the applicable local currency of the foreign entities. Assets and liabilities of the foreign entities are translated at period-end exchange rates. Statement of operations accounts are translated at the average exchange rate during the period. The effects of foreign currency translation adjustments are included in other comprehensive loss, which is a component of accumulated other comprehensive loss in stockholders' equity. All significant intercompany accounts and transactions have been eliminated in consolidation. Heat accounts for its less than 100% interest in accordance with U.S. GAAP. Accordingly, the Company presents non-controlling interest as a component of stockholders' equity on its consolidated balance sheets and reports non-controlling interest net loss under the heading "net loss – non-controlling interest" on its consolidated statements of operations and comprehensive loss. At September 30, 2019 and December 31, 2018, Heat held an 85% controlling interest in Pelican and a 100% interest in Heat I. During the nine months ended September 30, 2018, Heat held an 80% controlling interest in Pelican and a 92.5% controlling interest in Heat I. 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. For the nine months ended September 30, 2019 all net losses attributable to non-controlling interests relate to Pelican.

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

Liquidity and Capital Resources

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company has an accumulated deficit in excess of $100 million as of September 30, 2019, a net loss for the three months ended September 30, 2019 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 grant provided by the Cancer Prevention and Research Institute of Texas or CPRIT. 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.

These factors raise substantial doubt about the Company's ability to continue as a going concern for one year after the financial statements are issued. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company intends to continue to consider multiple alternatives, including, but not limited to, additional equity financings such as sales of its common stock under the B. Riley FBR, Inc. At Market Issuance 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 continually evaluates various cost-saving measures considering its cash requirements in order to focus resources on its product candidates and ranks its development programs based upon progress in clinical development, among other things. These rankings could result in a reduction, delay, or elimination of certain of its research and development programs and are subject to change based upon future events. The Company will need to generate significant revenues to achieve profitability, and it may never do so.

Cash Equivalents and Restricted Cash

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

Short-term Investments

The Company's short-term investments are equity securities and are carried at their fair value based on quoted market prices. Realized and unrealized gains and losses on equity securities are included in net earnings in the period earned or incurred.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates are used for, but not limited to, useful lives of fixed assets, contingent consideration, 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.

Goodwill and In-Process Research and Development

The Company classifies intangible assets into three categories: (1) intangible assets with definite lives subject to amortization, (2) intangible assets with indefinite lives not subject to amortization and (3) goodwill. The Company determines the useful lives of definite-lived intangible assets after considering specific facts and circumstances related to each intangible asset. Factors the Company considers when determining useful lives include the contractual term of any agreement related to the asset, the historical performance of the asset, and other economic facts; including competition and specific market conditions. Intangible assets that are deemed to have definite lives are amortized, primarily on a straight-line basis, over their estimated useful lives. Intangible assets that are deemed to have indefinite lives, including goodwill, are reviewed for impairment annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment test for indefinite-lived intangibles, other than goodwill, consists of a comparison of the fair value of the intangible asset with its carrying amount. If the carrying amount exceeds the fair value, an impairment charge is recognized in an amount equal to that excess. Indefinite-lived intangible assets, such as goodwill, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence a potential impairment exists, using a fair value-based test. Pursuant to ASU 2017-04, the Company must record a goodwill impairment charge if a reporting unit's carrying value exceeds its fair value. See note 7 regarding impairment at September 30, 2019.

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

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 reassesses the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long term liabilities in the consolidated balance sheets.

Research and Development

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

Revenue Recognition

The Company earns substantially all its revenue from a research grant from CPRIT. The Company's contract with CPRIT relates to 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.

CPRIT advances grant funds upon request by the Company consistent with the agreed upon amounts and schedules as provided in the contract. Funds received are reflected in deferred revenue as a liability until revenue is earned. Grant revenue is earned and recognized when qualifying costs are incurred.

Prepaid Expenses and Other Current Assets

The Company's prepaid expenses and other current assets consist primarily of the amount paid in advance for cGMP production of Pelican's PTX-35 antibody and PTX-15 fusion protein, insurance and the Company's contribution to tenant improvements.

Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the carrying amounts of assets and liabilities and their respective tax bases, operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. 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 2018 Annual Report and have not changed significantly since such filing.

Recently Issued Accounting Pronouncements

In November 2018, the FASB issued ASU 2018-18: *Collaborative Arrangements* (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. This ASU, in part, requires that certain transactions with collaboration partners be excluded from revenue recognized under Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019. The Company is evaluating the impact of this standard and does not plan early adoption of this standard.

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

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

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

2. Acquisition of Pelican Therapeutics

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

Under the Pelican stock acquisition 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. The fair value of these future milestone payments is reflected in the contingent consideration account under current liabilities with the non-current portion under long term liabilities on the balance sheet. The estimated fair value of the contingent consideration was determined using a probability-weighted income approach, at a discount of 3.9% based on the median yield of publicly traded non-investment grade debt of companies in the pharmaceutical industry. The Company estimates the fair value of the contingent consideration on a quarterly basis. At the time of the Pelican acquisition, the Company's CEO and certain affiliated entities as well as two of the Company's directors and certain affiliated entities directly or indirectly owned shares of Pelican common stock purchased by the Company. As a result, approximately 51% of any such milestone payments will be paid to the Company's CEO, two of its directors and affiliated companies.

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

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

3. Fair Value of Financial Instruments

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

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

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

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

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

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

As of September 30, 2019 and December 31, 2018, the fair values of cash, accounts payable, and accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. The Company's short-term investments consist of Level I securities which are comprised of highly liquid money market funds. The estimated fair value of the short-term investments was based on quoted market prices. There were no transfers between fair value hierarchy levels during the quarters ended September 30, 2019 or 2018.

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

	As of September 30, 2019			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ 5,683,446	$ 5,683,446	—	—
Liabilities:				
Contingent consideration	$ 3,833,515	—	—	$ 3,833,515

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

The following table summarizes the change in fair value, as determined by Level 3 inputs, for all assets and liabilities using unobservable Level 3 inputs for the nine months ended September 30, 2019:

	Contingent Consideration
Balance at December 31, 2018	$ 3,105,225
Change in fair value	728,290
Balance at September 30, 2019	$ 3,833,515

The change in the fair value of the contingent consideration for the nine months ended September 30, 2019 was primarily because of the increase in the estimated probability of achieving the initial milestone, a change in discount rate and the passage of time on the fair value measurement. Adjustments associated with the change in fair value of contingent consideration are included in the Company's consolidated statement of operations and comprehensive loss.

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements of contingent consideration classified as Level 3 as of September 30, 2019:

	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent Consideration	Probability weighted income approach	Milestone dates	2020-2026
		Discount rate	3.9%
		Probability of occurrence	23% to 86%

The Company measures certain non-financial assets on a non-recurring basis, including goodwill and in-process R&D. As a result of those measurements, during the three and nine months ended September 30, 2019, goodwill with a total carrying value of $2.2 million was written down to its estimated fair value of $1.5 million and an impairment charge of $0.7 million was recorded. The Company uses a present value technique to estimate the fair value of these assets. This analysis requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital.

4. Short-Term Investments

The following summarizes information about short term investments at September 30, 2019 and December 31, 2018, respectively:

	Amortized Cost	Gross Unrealized Gains (Losses)	Estimated Fair Value
September 30, 2019			
Mutual fund	$ 5,677,989	$ 5,457	$ 5,683,446
December 31, 2018			
Mutual fund	$ 5,570,158	$ (131)	$ 5,570,027

5. Prepaid Expenses and Other Current Assets

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

	September 30, 2019	December 31, 2018
Prepaid lease costs	$ 257,916	$ —
Prepaid manufacturing expense	134,500	559,110
Prepaid insurance	92,972	284,931
Prepaid clinical study expenses	172,075	—
Other prepaid expenses and current assets	77,325	117,276
	$ 734,788	$ 961,317

6. 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 five to seven years. Expenditures for maintenance and repairs are charged to expense as incurred.

Property and equipment consist of the following at:

	September 30, 2019	December 31, 2018
Lab equipment	$ 1,290,677	$ 1,218,532
Leasehold improvements	9,445	9,445
Computers	49,603	38,589
Furniture and fixtures	118,305	58,146
Total	1,468,030	1,324,712
Accumulated depreciation	(858,114)	(681,566)
Property and equipment, net	$ 609,916	$ 643,146

Depreciation expense was $54,826 and $176,548 for the three and nine months ended September 30, 2019, respectively, and $62,827 and $171,235 for the three and nine months ended September 30, 2018, respectively.

7. Goodwill and In-Process R&D

Goodwill of $2.2 million and in-process R&D of $5.9 million were recorded in connection with the acquisition of Pelican, as described in Note 2.The Company performs an annual impairment test at the reporting unit level. However, during the three months ended September 30, 2019, the Company experienced a sustained decline in the quoted market price of the Company's common stock and as a result the Company determined that as of September 30, 2019 it was more likely than not that the carrying value of these acquired intangibles exceeded their estimated fair value. Accordingly, the Company performed an interim impairment analysis as of that date using the income approach. This analysis required significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital. Pursuant to ASU 2017-04, the Company recorded a goodwill impairment charge for the excess of the reporting unit's carrying value over its fair value. During the three and nine months ended September 30, 2019, goodwill with a total carrying value of $2.2 million was written down to its estimated fair value of $1.5 million and an impairment charge of $0.7 million was recorded. The Company determined that the fair value of the IPR&D was in excess of its carrying value as of September 30, 2019 and therefore no impairment was recorded for the IPR&D.

8. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following:

	September 30, 2019	December 31, 2018
Compensation and related benefits	$ 130,920	$ 628,147
Other accrued operating expenses	1,150,991	1,049,904
	$ 1,281,911	$ 1,678,051

9. Stockholders' Equity

Common Stock Warrants

During the three months and nine months ended September 30, 2019, there were no changes in the Company's outstanding warrants. As of September 30, 2019, the Company has outstanding warrants to purchase 9,030,730 shares of common stock issuable at a weighted-average exercise price of $1.89 per share.

Equity Compensation Plans

The Company maintains various equity compensation plans with substantially similar provisions under which it may award employees, directors and consultants incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock based awards with terms established by the Compensation Committee of the Board of Directors which has been appointed by the Board of Directors to administer the plans. In July 2019, the Company's shareholders approved an increase of 4,000,000 shares in the number of shares available for grant. As of September 30, 2019, there were 4,021,160 shares remaining available for grant under these plans.

Stock Options

The following is a summary of the stock option activity for the nine months ended September 30, 2019:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2018	465,303	$ 11.60
Granted	2,920,021	1.03
Exercised	(2,000)	1.06
Expired	(16,821)	4.43
Forfeited	(203,149)	1.46
Outstanding, September 30, 2019	3,163,354	$ 2.54

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2019 was $0.91. 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 three months ended September 30, 2019:

Dividend yield	0.0%
Expected volatility	132.0%
Risk-free interest rate	2.5%
Expected lives (years)	5.5

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

Expected dividend yield was considered to be 0% in the option pricing formula since the Company had not paid any dividends and had no plans to do so in the future. As required by ASC 718, the Company reviews recent forfeitures and stock compensation expense. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Additionally, the Company conducts a sensitivity analysis of the forfeiture rate. Based on these evaluations the Company currently does not apply a forfeiture rate.

The following table summarizes information about stock options outstanding at September 30, 2019:

Options Outstanding			Options Vested and Exercisable		
Options	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Options	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
3,163,354	8.9	$2.54	1,346,174	8.4	$4.18

Restricted Stock

The following is a summary of restricted stock and restricted stock unit activity for the nine months ended September 30, 2019:

	Shares
Unvested, December 31, 2018	56,520
Granted	1,579,179
Vested	(747,805)
Forfeited	(49,465)
Unvested, September 30, 2019	838,429

10. Grant Revenue

In June 2016, Pelican entered into a cancer research grant contract or Grant Contract with CPRIT, under which CPRIT awarded a grant not to exceed $15.2 million for use in developing cancer treatments by targeting a novel T-cell costimulatory receptor (namely, TNFRSF25). The Grant Contract covers a period from June 1, 2016 through November 30, 2019, as amended. 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 remaining $6.9 million is expected to be requested and received following IND completion.

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

Through September 30, 2019, all $8.3 million of grant funding received to date has been recognized as revenue.

11. Net Loss Per Share

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

For the three and nine months ended September 30, 2019 and 2018, all the Company's common stock options, unvested restricted stock units and warrants were anti-dilutive and therefore have been excluded from the diluted calculation.

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share in the three and nine months ended September 30 due to their anti-dilutive effect:

	2019	2018
Outstanding stock options	3,163,354	465,406
Restricted stock subject to forfeiture and restricted stock units	838,429	61,144
Outstanding common stock warrants	9,030,730	4,430,730

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, 2019, $0.9 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 in-process R&D costs. Specifically, the prior & 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 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, 2019, and December 31, 2018, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense. As of September 30, 2019, and December 31, 2018, the Company had no such accruals.

13. Leases

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

The Company leases office space under operating leases. Total lease costs, consisting of fixed operating lease costs, in the three and nine months ended September 30, 2019 amounted to $66,895 and $200,684, respectively. As of September 30, 2019, lease liabilities have been determined using a discount rate of approximately 8.6%. The rate implicit in the Company's leases is not readily determinable. Accordingly, the Company uses its estimated incremental borrowing rate, which represents the rate of interest that it would pay to borrow on a collateralized basis over a similar term. As of September 30, 2019, the weighted-average remaining life of the Company's leases is approximately 3.4 years. Operating cash flows in the three and nine months ended September 30, 2019 include $69,138 and $205,401, respectively, of payments for amounts included in the measurement of operating lease liabilities.

Maturities of operating lease liabilities as of September 30, 2019 were as follows:

Year ending December 31:	
October 1 through December 31, 2019	$ 28,358
2020	115,580
2021	118,158
2022	120,737
2023	20,195
Total lease payments	403,028
Less: imputed interest	(52,738)
Present value of operating lease liabilities	$ 350,290

In April 2019, the Company entered into a 96-month lease for office and laboratory space that commenced upon the expiration of an existing lease in October 2019. Scheduled lease payments under the new lease total approximately $1.8 million. As of September 30, 2019, the Company had not taken control of the space and the lease term had not commenced. Accordingly, no right of use asset or lease liability related to the lease has been recorded as of this date. The Company expects to incur approximately $500,000 of the cost of improvements at commencement of the lease.

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, 2018 filed with the Securities and Exchange Commission on March 28, 2019 and Amendment No. 1 thereto filed with the SEC on April 24, 2019 (the "2018 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 focused on activating a patient's immune system against cancer through T-cell activation and expansion. Our T-cell Activation Platform (TCAP), includes two variations for intradermal administration, Immune Pan-antigen Cytotoxic Therapy (*ImPACT*®) and Combination Pan-antigen Cytotoxic Therapy (*ComPACT*™). HS-110 (viagenpumatucel-L) is our first biologic product candidate in a series of proprietary *ImPACT*® based immunotherapies designed to stimulate a patient's own T-cells to destroy cancer. HS-130 is an allogeneic ("off-the-shelf") cell line engineered to express the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T-cells, with the potential to augment antigen-specific CD8+ T-cell response. To further augment antigen experienced T-cell activation and expansion, we are also developing PTX-35, a novel T-cell co-stimulator agonist antibody targeting TNFRSF25 for systemic administration. These programs are designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. We have completed recruiting patients in our Phase 2 HS-110 non-small cell lung cancer (NSCLC) trial, have received U.S. Food & Drug Administration (FDA) clearance of an IND submission for our HS-130 program and anticipate an IND for our PTX-35 program. We are also providing preclinical, CMC development, and administrative support for these operations; while constantly focusing on protecting and expanding our intellectual property in areas of strategic interest.

We recently completed patient enrollment in our Phase 2 clinical trial for HS-110 in advanced NSCLC, that administered HS-110 in combination with either Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor nivolumab (Opdivo®) or more recently, Merck & Co., Inc's (Merck's) anti-PD1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®). In November we presented a poster at The Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting that had data that was obtained from a cohort of 56 NSCLC patients in our ongoing Phase 2 clinical trial. We also announced interim results of this study in June 2019. We believe that this data may represent the first Phase 2 data showing clinical activity of a checkpoint inhibitor combination in NSCLC patients whose disease has progressed after prior treatment with a checkpoint inhibitor (CPI). Our other programs are in preclinical and CMC development with an IND filing cleared by the FDA for HS-130 and an anticipated IND for PTX-35.

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

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

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

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

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

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

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

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

We have completed patient enrollment in our HS-110 Phase 2 combination immunotherapy trial, received clearance from the FDA of an IND submission for HS-130, advanced preclinical development of Pelican assets with an IND filing for PTX-35 on October 29,2019 and await FDA clearance, and provided general and administrative support for these operations while protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any revenue from product sales since our inception. We expect to continue to incur significant expenses and to incur increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

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

Recent Developments

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

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

- November 5, 2019, an abstract (the "Abstract") titled "Treating Advanced Non-Small Lung Cancer Patients after Checkpoint Inhibitor Treatment Failure with a Novel Combination of Viagenpumatucel-L (HS-110) plus Nivolumab" which had been submitted by us to The Society for Immunotherapy of Cancer's (SITC) in connection with its 34th Annual Meeting was published by SITC. On November 8, 2019, a poster was presented at SITC which included detailed data obtained from our ongoing phase 2 study of previously-treated NSCLC of HS-110 in combination with nivolumab (Cohort B). Patients in this cohort have progressed after ≥ 4 months of prior treatment with a checkpoint inhibitor. The study evaluates whether the addition of HS-110 to nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor therapy. Cohort B data presented below is based on 56 patients in the intent-to-treat (ITT) population at the time of data cut-off:
  - Response rate by RECIST 1.1
    - Partial response (PR) in 7 patients (13%)
    - Stable disease (SD) in 26 patients (46%)
    - Disease control rate (DCR) was (59%)
  - Median overall survival (OS) was estimated at 11.8 months (95% CI; 6.6– not reached months) with 39 of the 56 patients censored (70% of patients still alive).
  - Median progression free survival (mPFS) was estimated at 3.2 months (95% CI; 1.9 - 4.0 months) with 17 patients censored.
  - Subset analysis based on Injection Site Reaction (ISR):
    - Patients who experienced an ISR versus those who did not experience ISR:
      - Improved PFS (3.7 vs 1.8 months; HR 0.21, *p =0.00681*)
      - Improved OS (12 vs 5 months; HR 0.16, *p=0.0005*)
  - Combination of HS-110 and nivolumab was well tolerated by patients.
    - 92% of adverse events (AEs) were mild (Grade 1 or 2).
    - There were only four grade 4 events, and no grade 5 AEs.

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 consolidated financial statements contained herein and to our audited consolidated financial statements contained in our 2018 Annual Report 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;
- In-process R&D;
- Goodwill impairment;
- Income tax;
- Contingent consideration;
- Stock-based compensation;
- Research and development costs, including clinical and regulatory cost; and
- Recent accounting pronouncements.

RESULTS OF OPERATIONS

Comparison of the Three Months ended September 30, 2019 and 2018

Revenues. For the three months ended September 30, 2019, we recognized no grant revenue under the CPRIT grant, as we had previously recognized in revenue all funding received through the contract year ended May 2019. Grant funding for program expenses incurred after May 2019 is subject to grantor approval. We expect to receive the final tranche of grant funding following IND completion. As of September 30, 2019, we had no deferred revenue for proceeds previously received. We recognized $1.1 million of grant revenue related to CPRIT during the three months ended September 30, 2018. 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 decreased to $3.1 million for the quarter ended September 30, 2019 from $4.4 million in the quarter ended September 30, 2018. The components of R&D expense are as follows, in millions:

	Three Months Ended, September 30,	
	2019	2018
Programs		
HS-110	$ 0.8	$ 0.7
HS-130	0.2	0.2
PTX 35/15	0.7	2.5
Other programs	0.1	0.2
Unallocated research and development expenses	1.3	0.8
	$ 3.1	$ 4.4

- HS-110 expense increased $0.1 million for the three months ended September 30, 2019, primarily due to outsourced clinical trial support services and payments to investigator sites for ongoing clinical trials
- HS-130 expense for the three months ended September 30, 2019 was comparable to the 2018 period, as increased consulting and clinical expenses offset lower costs of clinical trial materials.
- PTX expense for the three months ended September 30, 2019 decreased significantly from the comparable 2018 period, primarily reflecting decreased manufacturing costs.
- Other programs include preclinical costs associated with our Zika program, T-cell costimulatory programs, and laboratory supplies.
- Unallocated research expenses in the three months ended September 30, 2019 increased compared to the 2018 period, primarily reflecting increased personnel costs, including stock-based compensation from 2019 stock awards.

General and administrative expense. General and administrative expense increased to $2.0 million for the quarter ended September 30, 2019 compared to $1.6 million for the quarter ended September 30, 2018. The increase is primarily attributable to increased personnel costs, including stock-based compensation expense, and increased consulting expenses.

Goodwill impairment loss. We perform an annual impairment test at the reporting unit level. However, during the three months ended September 30, 2019, we experienced a sustained decline in the quoted market price of our common stock and as a result we determined that as of September 30, 2019 it was more likely than not that the carrying value of these acquired intangibles exceeded their estimated fair value. Accordingly, we performed an interim impairment analysis as of that date using the income approach. This analysis required significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows, and a risk-adjusted weighted average cost of capital. Pursuant to ASU 2017-04, we recorded a goodwill impairment charge for the excess of the reporting unit's carrying value over its fair value. During the three and nine months ended September 30, 2019, goodwill with a total carrying value of $2.2 million was written down to its estimated fair value of $1.5 million and an impairment charge of $0.7 million was recorded. We determined that the fair value of the IPR&D was in excess of its carrying value as of September 30, 2019 and therefore no impairment was recorded for the IPR&D. There were no such charges in the 2018 period.

Change in fair value of contingent consideration. The change in fair value of contingent consideration was $0.5 million for the three months ended September 30, 2019, compared to $0.1 million in the three months ended September 30, 2018. The greater change in the 2019 period primarily reflects an increase in estimated probability factors for milestone achievement.

Total non-operating income. Other income decreased for the quarter ended September 30, 2019 compared to 2018. In 2019, other income reflects interest income on cash and short-term investment balances offset by foreign currency adjustments.

*Net loss attributable to Heat Biologics, Inc.*We had a net loss attributable to Heat Biologics, Inc. of $6.2 million, or $0.18 per basic and diluted share for the quarter ended September 30, 2019 compared to a net loss of $3.7 million, or $0.16 per basic and diluted share for the quarter ended September 30, 2018.

Comparison of the Nine months ended September 30, 2019 and 2018

Revenues. For the nine months ended September 30, 2019, we recognized $1.0 million of grant revenue for qualified expenditures under the CPRIT grant compared to $3.7 million of grant revenue related to CPRIT during the nine months ended September 30, 2018. The decrease in grant revenue in the current-year period primarily reflects decreased program spending and the conclusion of the CPRIT contract-year in May 2019.

Research and development expense. Research and development expenses decreased to $9.7 million for the nine months ended September 30, 2019 compared to $10.8 million for the nine months ended September 30, 2018. The components of R&D expense are as follows, in millions:

	Nine months Ended, September 30,	
	2019	2018
Programs		
HS-110	$ 2.5	$ 2.5
HS-130	0.3	0.7
PTX 35/15	2.8	4.7
Other programs	0.4	0.5
Unallocated research and development expenses	3.7	2.4
	$ 9.7	$ 10.8

- HS-110 expense was consistent with the prior-year period, reflecting the current-period mix of development activities, primarily decreased costs associated with the production of drug supplies offset by increased payments to investigator sites for ongoing clinical trials
- HS-130 expense represented primarily regulatory consulting in the current period and clinical trial materials in the 2018 period.
- PTX expense for 2019 decreased significantly compared to the 2018 period, primarily reflecting decreased manufacturing costs
- Other programs include preclinical costs associated with our Zika program, T-cell costimulatory programs, laboratory supplies and, in 2018, HS-410.

- The increase in unallocated research expenses primarily reflects personnel costs, including stock-based compensation from 2019 stock awards.

General and administrative expense. General and administrative expense increased to $7.2 million for the nine months ended September 30, 2019 compared to $4.7 million for the nine months ended September 30, 2018. The increase is primarily attributable to increased compensation expense, including stock-based compensation, and consulting expenses.

Goodwill impairment loss. We perform an annual impairment test at the reporting unit level. However, during the three months ended September 30, 2019, we experienced a sustained decline in the quoted market price of our common stock and as a result we determined that as of September 30, 2019 it was more likely than not that the carrying value of these acquired intangibles exceeded their estimated fair value. Accordingly, the we performed an interim impairment analysis as of that date using the income approach. This analysis required significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows, and a risk-adjusted weighted average cost of capital. Pursuant to ASU 2017-04, we recorded a goodwill impairment charge for the excess of the reporting unit's carrying value over its fair value. During the three and nine months ended September 30, 2019, goodwill with a total carrying value of $2.2 million was written down to its estimated fair value of $1.5 million and an impairment charge of $0.7 million was recorded. We determined that the fair value of the IPR&D was in excess of its carrying value as of September 30, 2019 and therefore no impairment was recorded for the IPR&D. There were no such charges in the 2018 period.

Change in fair value of contingent consideration. The change in fair value of contingent consideration was $0.7 million for the nine months ended September 30, 2019, comparable to the nine months ended September 30, 2018. In each period, the expense reflects an increase in estimated probability factors for milestone achievement.

Total non-operating income. Other income was $0.3 million for the nine months ended September 30, 2019 compared to $0.3 million for the nine months ended September 30, 2018. In 2019, other income was primarily related to interest income on cash and short-term investment balances. In 2018, other income is primarily related to the release of escrow funds to us for payment of liabilities related to the Pelican acquisition.

*Net loss attributable to Heat Biologics, Inc.*We had a net loss attributable to Heat Biologics, Inc. of $16.7 million, or $0.50 per basic and diluted share for the nine months ended September 30, 2019 compared to a net loss of $10.8 million, or $0.75 per basic and diluted share for the quarter ended September 30, 2018.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

Since our inception in June 2008, we have incurred significant losses and we have financed our operations with net proceeds from the private placement and public offering of our securities including preferred stock, common stock and debt. As of September 30, 2019, we had an accumulated deficit in excess of $100.0 million. We had net losses of $16.6 million and $12.4 million for the years ended December 31, 2018 and 2017, respectively, and a net loss of $17.1 million for the nine months ended September 30, 2019.

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 research and development activities 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. Upon achievement of the milestones set forth in our Pelican stock purchase agreement, we will be required to make milestone payments to participating Pelican shareholders, which include a $2.0 million upon first patient dosing in our first Phase 1 clinical trial of PTX-35 for an oncology indication. These factors raise substantial doubt about the Company's ability to continue as a going concern for one year after the financial statements are issued. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty

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 at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We are continually evaluating various cost-saving measures considering 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, 2019, we had approximately $15.0 million in cash and cash equivalents and short-term investments. Our research and development activities are conducted under our prudent cash management policies. To effectively manage our cash resources and determine allocations of cash among our development programs, we rank our development programs based upon, among other things, progress in clinical development. We place a higher level of priority on our programs that are further in clinical development. These rankings could result in a reduction, delay, or elimination of certain of our research and development programs and are subject to change based upon future events. Our current top priority is the completion of our Phase 2 clinical trial investigating HS-110 in combination with various checkpoint inhibitors in patients with advanced non-small cell lung cancer (NSCLC) as this program is furthest along in clinical development. Our next current highest priority is our CPRIT-funded PTX-35 program, for which we filed an IND on October 29, 2019 and await FDA clearance. Finally, our HS-130 program, for which we recently received FDA clearance of an IND application for a Phase 1 trial is our next current priority. We place a lower level of priority on our programs that are further from clinical development.

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 decrease in cash used in operating activities for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 is primarily due to a reduction of cash operating expenses, primarily for drug supplies and manufacturing, and the timing of payments to vendors.

Investing activities. We used $0.3 million of cash in investing activities in the nine months ended September 30, 2019 for lower levels of spending on lab equipment and for the purchase of short-term investments. We used $0.5 million of cash in investing activities during the nine months ended September 30, 2018 related to the purchase of property and equipment, as we established our San Antonio facilities per the CPRIT grant.

Financing activities. There were no significant cash inflows from financing activities for the nine months ended September 30, 2019. The source of $27.3 million of cash in the nine months ended September 30, 2018 was public offerings of stock, proceeds from the exercise of warrants and the issuance of common stock through an at-the-market Common Stock Sales Agreement (the "Underwriting Agreement") with H.C. Wainwright & Co., LLC., net of related stock issuance costs.

Current and Future Financing Needs

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

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals; and
- profitability of our clinical laboratory diagnostic and microbiology services business.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our equity or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. Potential sources of financing that we are pursuing include strategic relationships, public or private sales of our equity (including through the B. Riley FBR, Inc. At Market Issuance Sales Agreement, or FBR Sales Agreement) or debt and other sources. We cannot assure that we will meet the requirements for use of the FBR Sales Agreement especially in light of the fact that we are currently limited by our authorized number of shares of common stock and the rules of the SEC as to the number of shares of common stock that we can sell pursuant to the FBR Sales Agreement due to the market value of our common stock held by non-affiliates. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan, including accessing the CPRIT Grant. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

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.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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, 2019. 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. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. 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, 2019 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

We have a limited number of employees with accounting and reporting responsibilities. During the three months ended September 30, 2019, we appointed a new Vice President of Finance and we experienced changes in other accounting personnel with roles in our accounting and financial reporting processes. Other than such personnel changes, there were no changes 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, 2019 that have materially affected, or are 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 2018 Annual Report. Except as disclosed below, there have been no material changes from the risk factors and uncertainties disclosed in our 2018 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.

As of September 30, 2019, we had an accumulated deficit in excess of $100.0 million. We had net losses of $16.6 million and $12.4 million for the years ended December 31, 2018 and 2017, respectively, and a net loss of $17.1 million for the nine months ended September 30, 2019. We expect to continue to incur operating losses until such time, if ever, as we can achieve sufficient levels of revenue from operations. Our ability to achieve profitability will depend on us obtaining regulatory approval for our product candidates and market acceptance of our product offerings and our capacity to develop, introduce and sell our products to our targeted markets. There can be no assurance that any of our product candidates will be approved for commercial sale, or even if our product candidates are approved for commercial sale that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

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

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

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

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

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

We 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, 2019, our operating activities used net cash of approximately $12.6 million and as of September 30, 2019, our cash and cash equivalents and short-term investments were approximately $15.0 million. During the years ended December 31, 2018 and 2017, our operating activities used net cash of approximately $21.7 and $6.4 million, respectively. 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. 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 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 and short-term investments will allow us to continue 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 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 fund our future operations and milestone payments and we cannot be certain that funding will be available to us on acceptable terms on a timely basis, or at all. To meet our financing needs, we are considering multiple alternatives, including, but not limited to, current and additional equity financings, which we expect will include sales of common stock through the public offering of securities, at the market issuances, debt financings and/or funding from partnerships or collaborations. Our ability to raise capital through the sale of securities may be limited by our number of authorized shares of common stock and various rules of the SEC and The Nasdaq Capital Market that place limits on the number and dollar amount of securities that we may sell. Although we may seek to increase our number of authorized shares of common stock, there can be no assurance that we will obtain the requisite approval to effect any of such action. If we do not obtain such stockholder approval to effect a reverse stock split, we may be unable to meet the continued listing requirements of The Nasdaq Capital Market. If we do not obtain such stockholder approval to increase our number of authorized shares, we may be unable to issue additional shares of common stock or meet the requirements for use of at-market-issuance agreements, especially since that we are subject to the smaller reporting company requirements, or to complete any such transactions on acceptable terms or otherwise. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders, assuming we are able to sufficiently increase our authorized number of shares of common stock. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. If we fail to raise additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities or continue to maintain our listing on the Nasdaq Capital Market. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

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

Our shares of common stock are currently listed on the Nasdaq Capital Market. If we fail to satisfy the continued listing requirements of the Nasdaq Capital Market, such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder's equity requirement, the Nasdaq Capital Market may take steps to de-list our common stock. Any de-listing would likely have a negative effect on the price of our common stock and would impair stockholders' ability to sell or purchase their common stock when they wish to do so. On June 21, 2019, we received written notice from the Listing Qualifications Department of Nasdaq Stock Market LLC ("Nasdaq") notifying us that for the preceding 30 consecutive business days (May 9, 2019 through June 20, 2019), our common stock did not maintain a minimum closing bid price of $1.00 per share ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). The notice has no immediate effect on the listing or trading of our common stock which will continue to trade on the Nasdaq Capital Market under the symbol "HTBX". In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we have a compliance period of 180 calendar days, or until December 18, 2019, to regain compliance with Nasdaq Listing Rule 5550(a)(2). Compliance can be achieved automatically and without further action if the closing bid price of our common stock is at or above $1.00 for a minimum of ten consecutive business days at any time during the 180-day compliance period, in which case Nasdaq will notify us of our compliance and the matter will be closed. If, however, we do not achieve compliance with the Minimum Bid Price Requirement by December 18, 2019, we may be eligible for additional time to comply. In order to be eligible for such additional time, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and must notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period. At our annual meeting of stockholders held on July 23, 2019, we sought but did not obtain approval of a reverse stock split. No assurance can be given that that we will obtain sufficient votes to effect a reverse stock split. Furthermore, no assurance can be given that we will be able to satisfy our continued listing requirements and maintain the listing of our common stock on the Nasdaq Capital Market. We intend to attempt to take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any action that requires stockholder approval will be approved by our stockholders or that any action taken by us would result in our common stock meeting the NASDAQ listing requirements, or that any such action would stabilize the market price or improve the liquidity of our common stock.

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

We regularly review acquired intangible assets for impairment when events or changes in circumstances indicate that the carrying value may not be recoverable. We test goodwill and indefinite-lived intangible assets for impairment at least annually. Factors that may be considered a change in circumstances, indicating that the carrying value of the intangible assets may not be recoverable, include: macroeconomic conditions, such as deterioration in general economic conditions; industry and market considerations, such as deterioration in the environment in which we operate; cost factors, such as increases in labor or other costs that have a negative effect on earnings and cash flows; our financial performance, such as negative or declining cash flows or a decline in actual or planned revenue or earnings compared with actual and projected results of relevant prior periods; other relevant entity-specific events, such as changes in management, key personnel, strategy, or customers; and sustained decreases in share price. For example, during the three months ended September 30, 2019, we recorded a non-cash goodwill impairment charge of $737,000, which is discussed in Note 7 - "Goodwill and In-Process R&D."

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

On August 30, 2019, we issued 54,000 and 20,000 shares of our common stock to two consultants providing investor relations servicesThese shares were issued upon the exemption from the registration provisions of the Securities Act provided for by Section 4(a)(2) thereof for transactions not involving a public offering.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES .

Not Applicable.

ITEM 4. MINE SAFETY DISCLOSURES .

Not Applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

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

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Bylaws of Heat Biologics, Inc. dated as of October 17, 2019 (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on October 18, 2019 (File No. 001-35994))
10.1	Offer Letter by and between Heat Biologics, Inc. and William L. Ostrander, dated September 23, 2019 (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on September 24, 2019 (File No. 001-35994))
10.2	Amendment No. 1 to the Heat Biologics, Inc. 2018 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 4, 2019)
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.

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, 2019

By: /s/ Jeffrey A. Wolf
Jeffrey A. Wolf
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2019

By: /s/ William Ostrander
William Ostrander
Vice President of Finance
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14 OR RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey Wolf, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Heat Biologics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2019

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14 OR RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William Ostrander, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Heat Biologics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 14, 2019

By: /s/ William Ostrander
Name: William Ostrander
Title: Vice President of Finance
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Heat Biologics, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Quarterly Report on Form 10-Q of the Registrant for the quarter ended September 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 14, 2019

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Heat Biologics, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Quarterly Report on Form 10-Q of the Registrant for the quarter ended September 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 14, 2019

By: /s/ William Ostrander
Name: William Ostrander
Title: Vice President of Finance
(Principal Financial and Accounting Officer)