

**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, 2020

OR

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

For the transition period from _____ to _____

Commission file number: 001-35994

Heat Biologics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

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

**627 Davis Drive, Suite 400
Morrisville, NC**

(Address of Principal Executive Offices)

26-2844103

*(I.R.S. Employer
Identification No.)*

27560

(Zip Code)

(919) 240-7133

(Registrant's Telephone Number, including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	HTBX	The Nasdaq Stock Market, LLC <i>(The Nasdaq Capital Market)</i>

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting 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 5, 2020, there were 159,845,850 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, 2019 filed with the SEC on March 30, 2020. 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

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	(unaudited)	
Current Assets		
Cash and cash equivalents	\$ 24,808,083	\$ 9,039,887
Short-term investments	92,501,019	5,713,922
Accounts receivable	212,141	34,986
Prepaid expenses and other current assets	1,620,504	420,328
Total Current Assets	<u>119,141,747</u>	<u>15,209,123</u>
Property and Equipment, net	<u>720,396</u>	<u>559,410</u>
Other Assets		
In-process R&D	5,866,000	5,866,000
Goodwill	1,452,338	1,452,338
Operating lease right-of-use asset	2,123,414	2,287,500
Finance lease right-of-use asset	276,918	187,573
Deposits	129,505	394,637
Total Other Assets	<u>9,848,175</u>	<u>10,188,048</u>
Total Assets	<u>\$ 129,710,318</u>	<u>\$ 25,956,581</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 753,872	\$ 1,503,342
Deferred revenue, current portion	1,166,481	3,410,319
Contingent consideration, current portion	—	1,124,970
Contingent consideration, related party - current portion	—	454,364
Operating lease liability, current portion	271,703	216,832
Finance lease liability, current portion	106,409	49,104
Accrued expenses and other liabilities	1,503,899	1,676,467
Total Current Liabilities	<u>3,802,364</u>	<u>8,435,398</u>
Long Term Liabilities		
Other long-term liabilities	26,331	—
Derivative warrant liability	60,915	—
Deferred tax liability	361,911	361,911
Deferred revenue, net of current portion	240,000	200,000
Operating lease liability, net of current portion	1,374,141	1,519,574
Financing lease liability, net of current portion	187,881	142,667
Contingent consideration, net of current portion	2,131,830	1,653,197
Contingent consideration, related party - net of current portion	626,685	485,984
Total Liabilities	<u>8,812,058</u>	<u>12,798,731</u>
Commitments and Contingencies (Note 13)		
Stockholders' Equity		
Common stock, \$.0002 par value; 250,000,000 shares authorized, 157,021,194 and 33,785,999 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	31,402	6,757
Additional paid-in capital	245,740,939	118,173,843
Accumulated deficit	(124,195,893)	(104,597,748)
Accumulated other comprehensive loss	(35,910)	(11,250)
Total Stockholders' Equity - Heat Biologics, Inc.	<u>121,540,538</u>	<u>13,571,602</u>
Non-Controlling Interest	<u>(642,278)</u>	<u>(413,752)</u>
Total Stockholders' Equity	<u>120,898,260</u>	<u>13,157,850</u>
Total Liabilities and Stockholders' Equity	<u>\$ 129,710,318</u>	<u>\$ 25,956,581</u>

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,	
	2020	2019	2020	2019
Revenue:				
Grant and contract revenue	\$ 849,732	\$ 6,439	\$ 2,344,777	\$ 1,049,988
Operating expenses:				
Research and development	3,172,663	3,129,356	8,745,966	9,725,744
General and administrative	6,579,193	1,993,136	11,651,415	7,201,196
Goodwill impairment loss	—	737,000	—	737,000
Change in fair value of contingent consideration	229,000	502,000	1,045,000	728,290
Total operating expenses	<u>9,980,856</u>	<u>6,361,492</u>	<u>21,442,381</u>	<u>18,392,230</u>
Loss from operations	<u>(9,131,124)</u>	<u>(6,355,053)</u>	<u>(19,097,604)</u>	<u>(17,342,242)</u>
Change in fair value of warrant liability	(37,230)	—	(1,039,303)	—
Investor relations expense	—	—	(66,767)	—
Interest income	140,614	97,415	249,404	373,060
Other income (expense), net	111,307	(73,275)	127,599	(80,539)
Total non-operating income (loss)	<u>214,691</u>	<u>24,140</u>	<u>(729,067)</u>	<u>292,521</u>
Net loss before income taxes	(8,916,433)	(6,330,913)	(19,826,671)	(17,049,721)
Income tax expense	—	—	—	(45,178)
Net loss	<u>(8,916,433)</u>	<u>(6,330,913)</u>	<u>(19,826,671)</u>	<u>(17,094,899)</u>
Net loss - non-controlling interest	(64,824)	(136,315)	(228,526)	(413,955)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (8,851,609)</u>	<u>\$ (6,194,598)</u>	<u>\$ (19,598,145)</u>	<u>\$ (16,680,944)</u>
Net loss per share attributable to Heat Biologics, Inc.-				
Net loss per share attributable to Heat Biologics, Inc.-basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.18)</u>	<u>\$ (0.20)</u>	<u>\$ (0.50)</u>
Weighted-average number of common shares used in net loss per share attributable to common stockholders-				
Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc.—basic and diluted	143,728,870	33,650,829	96,481,271	33,255,535
Comprehensive loss:				
Net loss	\$ (8,916,433)	\$ (6,330,913)	\$ (19,826,671)	\$ (17,094,899)
Unrealized (loss) gain on foreign currency translation	(63,954)	63,711	(24,660)	72,134
Total comprehensive loss	<u>(8,980,387)</u>	<u>(6,267,202)</u>	<u>(19,851,331)</u>	<u>(17,022,765)</u>
Comprehensive loss attributable to non-controlling interest	(64,824)	(136,315)	(228,526)	(413,955)
Comprehensive loss - Heat Biologics, Inc.	<u>\$ (8,915,563)</u>	<u>\$ (6,130,887)</u>	<u>\$ (19,622,805)</u>	<u>\$ (16,608,810)</u>

See Notes to Consolidated Financial Statements

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

	Three Months Ended September 30, 2020					
	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Non-Controlling Interest	Total Stockholders' Equity
Balance at June 30, 2020	\$ 22,006	\$ 163,007,558	\$ (115,344,284)	\$ 28,044	\$ (577,454)	\$ 47,135,870
ATM raise	9,307	79,288,802	—	—	—	79,298,109
Stock issuance costs	—	(1,984,155)	—	—	—	(1,984,155)
Stock-based compensation	—	4,728,894	—	—	—	4,728,894
Exercise of warrants	86	699,843	—	—	—	699,929
Exercise of options	3	(3)	—	—	—	—
Other comprehensive loss	—	—	—	(63,954)	—	(63,954)
Net loss	—	—	(8,851,609)	—	(64,824)	(8,916,433)
Balance at September 30, 2020	\$ 31,402	\$ 245,740,939	\$ (124,195,893)	\$ (35,910)	\$ (642,278)	\$ 120,898,260

	Nine Months Ended September 30, 2020					
	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2019	\$ 6,757	\$ 118,173,843	\$ (104,597,748)	\$ (11,250)	\$ (413,752)	\$ 13,157,850
January 2020 investment offering, net of underwriters discounts	4,000	4,102,148	—	—	—	4,106,148
ATM raise	18,280	116,278,482	—	—	—	116,296,762
Issuance of common stock from vesting of restricted stock awards	328	(328)	—	—	—	—
Stock issuance costs	—	(3,076,915)	—	—	—	(3,076,915)
Stock-based compensation	—	6,050,094	—	—	—	6,050,094
Exercise of warrants	1,587	3,440,735	—	—	—	3,442,322
Exchange of warrants	447	772,883	—	—	—	773,330
Exercise of options	3	(3)	—	—	—	—
Other comprehensive income	—	—	—	(24,660)	—	(24,660)
Net loss	—	—	(19,598,145)	—	(228,526)	(19,826,671)
Balance at September 30, 2020	\$ 31,402	\$ 245,740,939	\$ (124,195,893)	\$ (35,910)	\$ (642,278)	\$ 120,898,260

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
Issuance of common stock	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—
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	3	18,894	—	—	—	18,897
Exercise of stock options	—	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 Cash Flows
(Unaudited)

	For the Nine Months Ended September 30,	
	2020	2019
Cash Flows from Operating Activities		
Net loss	\$ (19,826,671)	\$ (17,094,899)
Adjustments to reconcile net loss to net cash used in operating activities:		
Goodwill impairment loss	—	737,000
Depreciation and amortization	242,623	176,548
Noncash lease expense	73,524	—
Noncash interest expense	13,838	—
Noncash investor relations expense	66,767	—
Stock-based compensation	6,050,094	2,932,253
Change in fair value of common stock warrants	1,039,303	—
Change in fair value of contingent consideration	1,045,000	728,290
Unrealized gain on investments	(47,923)	(5,589)
Increase (decrease) in cash arising from changes in assets and liabilities:		
Accounts receivable	(173,447)	(9,002)
Prepaid expenses and other current assets	(1,199,730)	225,245
Accounts payable	(748,410)	971,062
Deferred revenue	(2,203,838)	(1,032,539)
Deferred tax liability	—	45,178
Accrued expenses and other liabilities	(201,199)	(316,317)
Other long-term liabilities	26,331	92,511
Deposits	265,132	(35,065)
Net Cash Used in Operating Activities	<u>(15,578,606)</u>	<u>(12,585,324)</u>
Cash Flows from Investing Activities		
Purchase of short-term investments	(95,034,396)	(107,830)
Sale of short-term investments	8,295,222	—
Purchase of property and equipment	(321,301)	(143,318)
Proceeds from disposal of property and equipment	2,168	—
Net Cash Used in Investing Activities	<u>(87,058,307)</u>	<u>(251,148)</u>
Cash Flows from Financing Activities		
Proceeds from public offering of common stock and warrants, net of issuance costs	6,600,970	—
Proceeds from the issuance of common stock, net of underwriting discounts and commissions	116,296,762	18,898
Proceeds from exercise of stock options	—	2,120
Proceeds from the exercise of warrants	675,675	—
Stock issuance costs	(3,076,915)	—
Payment of contingent consideration	(2,005,000)	—
Proceeds from PPP loan	702,000	—
Repayment of PPP loan	(702,000)	—
Repayments on principal of finance lease	(85,140)	—
Net Cash Provided by Financing Activities	<u>118,406,352</u>	<u>21,018</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(1,243)</u>	<u>(4,376)</u>
Net Change in Cash and Cash Equivalents	<u>15,768,196</u>	<u>(12,819,830)</u>
Cash and Cash Equivalents – Beginning of Period	<u>9,039,887</u>	<u>22,154,251</u>
Cash and Cash Equivalents – End of Period	<u>\$ 24,808,083</u>	<u>\$ 9,334,421</u>
Supplemental Disclosure for Cash Flow Information:		
Operating lease right-of-use assets obtained with lease liabilities	<u>\$ 75,244</u>	<u>\$ 520,399</u>
Finance lease right-of-use assets obtained with lease liabilities	<u>\$ 173,822</u>	<u>\$ —</u>
Supplemental disclosure of non-cash investing and financing activities:		
Allocation of proceeds from public offering to warrant liabilities	<u>\$ 2,494,823</u>	<u>\$ —</u>
Cashless exercise of warrants classified as liabilities	<u>\$ 2,766,647</u>	<u>\$ —</u>
Cashless exchange of warrants classified as liabilities	<u>\$ 773,330</u>	<u>\$ —</u>

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 nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2020.

The consolidated financial statements as of and for the three and nine months ended September 30, 2020 and 2019 are unaudited. The balance sheet as of December 31, 2019 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, 2019 filed with the SEC on March 30, 2020 (the “2019 Annual Report”).

The accompanying unaudited consolidated financial statements as of and for the three and nine months ended September 30, 2020 and 2019 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., Skunkworx Bio, Inc. (formerly known as 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. At September 30, 2020 and December 31, 2019, Heat held 85% controlling interest in Pelican. 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.

Liquidity and Capital Resources

The Company has an accumulated deficit of approximately \$124.2 million as of September 30, 2020 and a net loss of approximately \$19.8 million for the nine months ended September 30, 2020 and has not generated significant operating revenue or positive cash flows from operations. The Company expects to incur significant expenses and continued losses from operations for the foreseeable future. The Company expects its expenses to increase in connection with its ongoing activities, particularly as the Company continues its research and development and advances its clinical trials of, and seeks marketing approval for, its product candidates. In addition, if the Company obtains marketing approval for any of its product candidates, the Company expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, the Company will need to obtain substantial additional funding in connection with its continuing operations. Adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts. To meet its capital needs, the Company intends to continue to consider multiple alternatives, including, but not limited to, additional equity financings such as sales of its common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on the Company’s current estimates, and the Company could use its available capital resources sooner than it currently expects. The Company is continually evaluating various cost-saving measures considering its cash requirements in order to focus resources on its product candidates. The Company will need to generate significant revenues to achieve profitability, and it may never do so. On April 23, 2020,

the Company filed a shelf registration statement on Form S-3 (the "Registration Statement"). Pursuant to the Registration Statement, the Company may offer and sell securities having an aggregate public offering price of up to \$150 million. In connection with the filing of the Registration Statement, the Company also entered into an amendment to its sales agreement ("Common Stock Sales Agreement") with B. Riley FBR, as sales agent, pursuant to which the Company may issue and sell shares of its common stock under an at-the-market (the "ATM") offering program. On August 24, 2020, the Company amended and restated the Common Stock Sales Agreement (the "Amended and Restated Common Stock Sales Agreement") to include Cantor Fitzgerald & Co. ("Cantor") as an additional sales agent for the ATM. Pursuant to the ATM, the Company will pay B. Riley FBR or Cantor (each a "Designated agent" and collectively, the "Agents"), a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. As of September 30, 2020, the Company had approximately \$117.3 million in cash and cash equivalents and short-term investments, which it believes is sufficient to fund its operations for at least one year from date of this filing.

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

Risk and Uncertainties

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

In March 2020, the World Health Organization declared COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, and any related adverse public health developments, has adversely affected workforces, economies, and financial markets globally, potentially leading to an economic downturn. It has also disrupted the normal operations of many businesses. With the global spread of the ongoing COVID-19 pandemic, the Company has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its business. The extent to which the COVID-19 pandemic impacts the Company's business, the clinical development of the Company's products, the business of the Company's suppliers and other commercial partners, the Company's corporate development objectives and the value of and market for the Company's common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The Company's in human phase 1 trial of HS-130 was subject to an approximate 8 week enrollment pause in April and May 2020 due to lack of personal protection equipment ("PPE") at a clinical site. The site ceased all non-critical/non-essential patient procedures until PPE supplies were available. Enrollment resumed and no delays in overall development milestones are expected for HS-130.

The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, to the extent the ongoing COVID-19 pandemic adversely affects the Company's business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties which the Company faces.

Cash and Cash Equivalents

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

Derivative Financial Instruments

The Company has issued common stock warrants in connection with the execution of certain equity financings. The fair value of the warrants, which were deemed to be derivative instruments, was recorded as a derivative liability under the provisions of ASC Topic 815 Derivatives and Hedging ("ASC 815") because they are not considered indexed to the Company's own stock. Subsequently, the liability is adjusted to fair value as of the end of each reporting period and the changes in fair value of derivative liabilities are recorded in the consolidated statements of operations and comprehensive loss under the caption "Change in fair value of warrant liability." See Note 3 for additional information.

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

The fair value of warrants was affected by changes in inputs to the Monte Carlo simulation model including the Company's stock price, expected stock price volatility, the remaining term, and the risk-free interest rate. This model uses Level 3 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At September 30, 2020, the fair value of such warrants was approximately \$60.9 thousand, which is classified as a long-term derivative warrant liability on the Company's consolidated balance sheets.

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, valuing warrants, income taxes and stock-based compensation. Actual results may differ from those estimates.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation in the consolidated financial statements and accompanying notes to the consolidated financial statements including the related party contingent consideration payable, which is now presented as a separate line item on the Company's consolidated balance sheets.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed the operations and managed the business as one segment.

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. No impairment existed at September 30, 2020.

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 of its revenue from a research grant from the Cancer Prevention and Research Institute of Texas (CPRIT). The Company's contract with CPRIT relates to Pelican developing a human TNFRSF25 agonist antibody for use in cancer patients through research and development efforts and the grant of a noncommercial license of the 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.

On January 7, 2020, the Company was awarded a grant of up to \$224,713 from the NIH. The NIH grant provides funding for continued development of the Company's technologies for PTX-35. The grant funds will be made available by the NIH to the Company as allowable expenses are incurred. For the three and nine months ended September 30, 2020, the Company incurred approximately \$0.1 million of allowable expenses under the NIH grant and recognized a corresponding amount of grant revenues.

Prepaid Expenses and Other Current Assets

The Company's prepaid expenses and other current assets consist primarily of the amount paid in advance for manufacturing activities, clinical trial support, and insurance.

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 2019 Annual Report and have not changed significantly since such filing.

Recently Issued Accounting Pronouncements

In January 2020, the FASB issued ASU 2020-01, Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)-Clarifying the Interactions between Topic 321, Topic 323, and Topic 815 (a consensus of the Emerging Issues Task Force), which addresses the accounting for the transition into and out of the equity method and measuring certain purchased options and forward contracts to acquire investments. ASU 2020-01 is effective for fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the expected impact of this standard but does not expect it to have a material impact on its consolidated financial statements upon adoption.

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes (ASU 2019-12), which simplifies the accounting for income taxes by removing certain exceptions to the general principles of Topic 740, Income

Taxes, and also improves consistency of application by clarifying and amending existing guidance. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the expected impact of this standard but does not expect it to have a material impact on its consolidated financial statements upon adoption.

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. The Company estimates the fair value of the contingent consideration on a quarterly basis. At the time of the Pelican acquisition, the Company's CEO and certain affiliated entities as well as two of the Company's directors and certain affiliated entities directly or indirectly owned shares of Pelican common stock purchased by the Company. As a result, approximately 22.7% of any such milestone payments will be paid to certain directors of the Company which is presented separately on the balance sheet as contingent consideration, related party - net of current portion. On June 22, 2020, we achieved the first milestone when we dosed the first patient in the first Phase 1 clinical trial of PTX-35.

Goodwill was calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill resulting from this acquisition related largely to synergies expected from combining the operations. The goodwill is not deductible for income tax purposes. In-process 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 its current 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 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 changes in the fair value of liability classified warrants are included in net loss for the respective periods. Because some of the inputs to our valuation model are either not observable or are not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability is classified as Level 3 in the fair value hierarchy. The Company's cash equivalents are classified within Level I of the fair value hierarchy.

As of September 30, 2020 and December 31, 2019, 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, 2020 or 2019.

In January 2020, the Company issued warrants in connection with the public offering of common stock (the "January 2020 Warrants"). Pursuant to the terms of these warrants, the warrants were not considered indexed to the Company's own stock and therefore are required to be measured at fair value and reported as a liability in the consolidated balance sheets. Additionally, upon the closing of the January 2020 offering, 3,357,166 previously outstanding warrants were required to be classified as a liability. The fair value of the warrant liability is based on the Monte Carlo methodology. The Company is required to revalue the warrants at each reporting date with any changes in fair value recorded on our consolidated statement of operations and comprehensive loss. The valuation of the warrants is classified under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. In order to calculate the fair value of the warrants, certain assumptions were made, including the selling price or fair market value of the underlying common stock, risk-free interest rate, volatility, and remaining life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimated a volatility factor utilizing a weighted average of comparable published betas of peer companies. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity.

The Black Scholes model was used to value these warrants before the equity to liability reclassification and the Monte Carlo simulation was used to value the warrants after the equity to liability reclassification. The following weighted average assumptions were used:

	January 21, 2020	
Current stock price	\$	0.33
Estimated volatility of future stock price		124 %
Risk free interest rate		1.53 %
Expected term		3.7 years

During the nine months ended September 30, 2020, 3,291,666 warrants were exchanged for 2,238,332 shares of common stock. As of September 30, 2020, there were a total of 65,500 warrants outstanding that were reported as a liability on the consolidated balance sheet.

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

Description	As of September 30, 2020			
	Total	Level 1	Level 2	Level 3
Assets:				
Short-term investments	\$ 92,501,019	\$ 92,501,019	—	—
Liabilities:				
Contingent consideration	\$ 2,758,515	—	—	\$ 2,758,515
Warrant liability	\$ 60,915	—	—	\$ 60,915

Description	As of December 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Short-term investments	\$ 5,713,922	\$ 5,713,922	—	—
Liabilities:				
Contingent consideration	\$ 3,718,515	—	—	\$ 3,718,515

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, 2020:

	Contingent Consideration	Warrant Liability
Balance at December 31, 2019	\$ 3,718,515	\$ —
Fair value at issuance	—	2,494,823
Reclassification of warrants from equity to liability due to modification	—	869,078
Reclassification of warrant liability to equity upon cashless exercise of warrants	—	(2,766,647)
Reclassification of warrant liability to equity upon exchange of warrants	—	(1,575,642)
Payout of contingent consideration	(2,005,000)	—
Change in fair value	1,045,000	1,039,303
Balance at September 30, 2020	\$ 2,758,515	\$ 60,915

The change in the fair value of the contingent consideration for the nine months ended September 30, 2020 was primarily due to the milestone payment to Pelican stockholders, the increase in the estimated probability of achieving the secondary milestone, a change in discount rate and the passage of time on the fair value measurement. The change in fair value of the warrant liability for the nine months ended September 30, 2020 was primarily due to increases in the fair value of the underlying stock. Adjustments associated with the change in fair value of contingent consideration and warrant liability 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, 2020:

	As of September 30, 2020		
	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent Consideration	Probability weighted income approach	Milestone dates	2022-2031
		Discount rate	8.56%
		Probability of occurrence	2.7% to 68%

The following table presents quantitative information about the inputs used in the valuation for the Company's fair value measurement of the warrant liability classified as Level 3 as of September 30, 2020:

	<u>September 30, 2020</u>
Current stock price	\$ 1.24
Estimated volatility of future stock price	137.77 %
Risk free interest rate	0.22 %
Contractual term	3.16 years

The Company measures certain non-financial assets on a non-recurring basis, including goodwill and in-process R&D. As a result of those measurements, during the year ended December 31, 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

Short-term investments consist of equity securities with a maturity of greater than three months when acquired. The Company holds its securities at fair value as of September 30, 2020 and December 31, 2019. Unrealized gains and losses on securities are reported in the statement of operations and comprehensive loss. Short-term investments at September 30, 2020 and December 31, 2019 consisted of mutual funds with fair values of \$92.5 million and \$5.7 million, respectively.

5. Prepaid Expenses and Other Current Assets

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

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Prepaid manufacturing expense	\$ 244,582	\$ 148,156
Prepaid insurance	832,379	120,851
Prepaid preclinical and clinical expenses	356,582	22,319
Other prepaid expenses and current assets	186,961	109,843
Other current assets	—	19,159
	<u>\$ 1,620,504</u>	<u>\$ 420,328</u>

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:

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Lab equipment	\$ 1,601,709	\$ 1,311,853
Computers	62,380	53,065
Furniture and fixtures	62,747	50,453
Leasehold improvements	22,563	14,259
Total	1,749,399	1,429,630
Accumulated depreciation	(1,029,003)	(870,220)
Property and equipment, net	<u>\$ 720,396</u>	<u>\$ 559,410</u>

Depreciation expense was \$58,853 and \$158,095 for the three and nine months ended September 30, 2020, respectively, and \$54,826 and \$176,548 for the three and nine months ended September 30, 2019, 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 as of April 1st of each fiscal year. As of April 1, 2020, the Company qualitatively assessed whether it is more likely than not that the respective fair value of the reporting unit is less than its carrying amount, including goodwill. Based on that assessment, the Company determined that this condition does not exist. As such, performing the first step of the two-step test impairment test was unnecessary. No impairment was recorded during the quarter ended September 30, 2020.

However, during the year ended December 31, 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 December 31, 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 year ended December 31, 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.

8. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following:

	September 30, 2020	December 31, 2019
Accrued preclinical and clinical trial expenses	\$ 627,604	\$ 1,156,618
Compensation and related benefits	186,363	303,870
Other expenses	689,932	215,979
	<u>\$ 1,503,899</u>	<u>\$ 1,676,467</u>

9. Stockholders' Equity

Underwritten Registered Offering

On January 21, 2020, the Company closed on a public offering consisting of 20,000,000 shares of common stock together with Warrants to purchase 10,000,000 shares of common stock. The gross proceeds to the Company from this offering were approximately \$7,000,000, before deducting underwriting discounts, commissions, and other offering expenses.

The Company has accounted for the warrants as liabilities and recorded them at fair value in our consolidated balance sheets (see Note 3).

At-The-Market-Offering

From January 1, 2020 to September 30, 2020 the Company sold approximately 91,399,427 shares of common stock under the Common Stock Sales Agreement, and the Amended and Restated Common Stock Sales Agreement, at an average price of approximately \$1.24 per share, raising aggregate net proceeds of approximately \$113,386,822 after deducting an aggregate commission up to 3%.

Common Stock Warrants

During the nine months ended September 30, 2020, 10,000,000 January 2020 warrants were exercised for 7,500,000 shares of common stock, and 3,291,666 previously outstanding warrants were exchanged for 2,238,332 shares of common stock. As of September 30, 2020, the Company has outstanding warrants to purchase 5,739,064 shares of common stock issuable at a weighted-average exercise price of \$2.04 per share.

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

	Common Stock Warrants
Outstanding, December 31, 2019	9,030,730
Issued	10,000,000
Exercised	(10,000,000)
Exchanged	(3,291,666)
Outstanding, September 30, 2020	<u>5,739,064</u>

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. At the 2020 Special Meeting of Stockholders, the stockholders approved an amendment to the Plan to increase the number of shares by 4,000,000. In August 2020, the Company's shareholders approved an increase of 15,000,000 shares in the number of shares available for grant. As of September 30, 2020, there were 13,727,222 shares remaining available for grant under these plans.

Accounting for Stock-Based Compensation:

Stock Compensation Expense - For the three and nine months ended September 30, 2020, the Company recorded \$4.7 million, and \$6.1 million of stock-based compensation expense, respectively. For the three and nine months ended September 30, 2019, the Company recorded \$0.5 million, and \$2.9 million of stock-based compensation expense respectively. No compensation expense of employees with stock awards was capitalized during the three and nine months ended September 30, 2020 and 2019.

Stock Options - Under the Plan, the Company has issued stock options. A stock option grant gives the holder the right, but not the obligation to purchase a certain number of shares at a predetermined price for a specific period of time. The Company typically issues options that vest over four years in equal installments beginning on the first anniversary of the date of grant. Under the terms of the Plan, the contractual life of the option grants may not exceed ten years. During the nine months ended September 30, 2020 and 2019, the Company issued options that expire ten years from the date of grant.

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

The following weighted-average assumptions were used for option grants during the three and nine months ended September 30, 2020 and 2019:

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

- **Expected life of options** – The expected term represents the period that the Company’s stock option grants are expected to be outstanding. The Company elected to utilize the “simplified” method to estimate the expected term. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.
- **Risk-free interest rate** – The rate is based on U.S. Treasury interest rates at the time of the grant whose term is consistent with the expected life of the stock options.
- **Dividend yield** – The expected dividend yield was considered to be 0% in the option pricing formula since the Company had not paid any dividends and had no plan to do so in the future.
- **Forfeitures** – As required by ASC 718, the Company reviews recent forfeitures and stock compensation expense. Forfeitures are estimated at the time of the 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 weighted-average assumptions used in our calculations of fair value for the nine months ended September 30, 2020 and 2019:

	2020	2019
Dividend yield	— %	— %
Expected volatility	96.26 %	132.00 %
Risk-free interest rate	0.52 %	2.50 %
Expected lives (years)	5.4 years	5.5 years

Stock Option Activity - The weighted-average fair value of options granted during the nine months ended September 30, 2020 and 2019, as determined under the Black-Scholes valuation model, was \$0.90 and \$0.91, respectively.

The following is a summary of the stock option activity for the nine months ended September 30, 2020:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Stock options outstanding at December 31, 2019	3,063,636	\$ 2.56	
Granted	6,164,100	1.22	
Exercised	(17,187)	0.53	
Forfeited/Expired	(53,684)	1.90	
Stock options outstanding at September 30, 2020	<u>9,156,865</u>	\$ 1.67	9.1 Years
Stock options exercisable at September 30, 2020	<u>5,921,313</u>	\$ 2.14	9.1 Years

Unrecognized compensation expense related to unvested stock options was \$2.0 million as of September 30, 2020, which is expected to be recognized over a weighted-average period of 1.6 years and will be adjusted for forfeitures as they occur.

Restricted Stock - Under the Plan, the Company has issued restricted stock. A restricted stock award is an issuance of shares that cannot be sold or transferred by the recipient until the vesting period lapses. Restricted stock issued to members of our Board of Directors and executives vest 50% on grant date, 30% on the first anniversary and 10% each anniversary thereafter. The grant date fair value of the restricted stock is equal to the closing market price of our common stock on the date of grant.

The following is a summary of restricted stock award activity for the nine months ended September 30, 2020:

	Shares	Weighted Average Fair Value
Restricted stock at December 31, 2019	1,254,653	\$ 0.86
Granted	2,380,000	0.46
Vested	<u>(1,622,720)</u>	0.62
Restricted stock at September 30, 2020	<u>2,011,933</u>	\$ 0.58

Restricted Stock Units - Under the Plan, the Company issued time-based RSUs. RSUs are not actual shares, but rather a right to receive shares in the future. The shares are not issued and the employee cannot sell or transfer shares prior to vesting and has no voting rights until the RSUs vest. The employees' time-based RSUs vest 25% on the award date and 25% each anniversary thereafter. The grant date fair value of the RSUs is equal to the closing market price of our common stock on the grant date. The Company recognizes the grant date fair value of RSUs of shares the Company expects to issue as compensation expense ratably over the requisite service period.

The following is a summary of stock unit activity for the nine months ended September 30, 2020:

	Shares	Weighted Average Fair Value
RSUs at December 31, 2019	30,026	\$ 4.33
Vested	(16,406)	4.73
Cancelled	<u>(338)</u>	5.20
RSUs at September 30, 2020	<u>13,282</u>	\$ 3.80

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, 2020, 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 and a third tranche of funding of \$5.4 million was received in December 2019. The remaining \$1.5 million will be awarded after the Company has fulfilled every requirement of the grant and the grant has been approved to be closed.

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.

On January 7, 2020, the Company was awarded a grant of up to \$224,713 from the NIH. The NIH grant provides funding for continued development of the Company's technologies for PTX-35. The grant funds will be made available by the NIH to the Company as allowable expenses are incurred.

Through September 30, 2020, \$12.6 million of grant funding received to date has been recognized as revenue.

11. Net Loss Per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the periods. Fully diluted net loss per common share is computed

using the weighted average number of common and dilutive common equivalent shares outstanding during the periods. Common equivalent shares consist of stock options and warrants that are computed using the treasury stock method.

For the quarters ended September 30, 2020 and 2019, all of the Company's common stock options, unvested restricted stock units and warrants are anti-dilutive and therefore have been excluded from the diluted calculation.

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

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Net loss	\$ (8,916,433)	\$ (6,330,913)	\$ (19,826,671)	\$ (17,094,899)
Net loss - Non-controlling interest	(64,824)	(136,315)	(228,526)	(413,955)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (8,851,609)</u>	<u>\$ (6,194,598)</u>	<u>\$ (19,598,145)</u>	<u>\$ (16,680,944)</u>
Weighted-average number of common shares used in net loss per share attributable to common stockholders —basic and diluted	<u>143,728,870</u>	<u>33,650,829</u>	<u>96,481,271</u>	<u>33,255,535</u>
Net loss per share attributable to Heat Biologics, Inc —basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.18)</u>	<u>\$ (0.20)</u>	<u>\$ (0.50)</u>

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, 2020 and 2019 due to their anti-dilutive effect:

	2020	2019
Outstanding stock options	9,156,865	3,163,354
Restricted stock subject to forfeiture and restricted stock units	2,025,215	838,429
Outstanding common stock warrants	5,739,064	9,030,730

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, 2020, \$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 R&D in process 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 unaudited condensed consolidated financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of September 30, 2020, and December 31, 2019, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of operations and comprehensive loss. As of September 30, 2020, and December 31, 2019, the Company had no such accruals.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act includes numerous provisions such as permitting NOL carryovers to offset 100% of taxable income for taxable years beginning before 2021 and a technical correction to the Tax Cuts and Jobs Act

allowing immediate expensing for Qualified Improvement Property through bonus depreciation. At this time management does not expect a substantial impact to deferred taxes.

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

The Company has determined, based on its preliminary analysis, that the provisions of CARES Act are not expected to impact our 2020 financials. The Company will monitor the updates, both to our business as well as guidance issued with respect to CARES Act that could impact the current interpretation of the issued provisions.

13. Leases

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.

The Company conducts its operations from leased facilities in Morrisville, North Carolina, and San Antonio, Texas, the leases for which will expire in 2027 and 2023, respectively. The leases are for general office space and require the Company to pay property taxes, insurance, common area expenses and maintenance costs.

On October 1, 2019, the commencement date of our Morrisville, North Carolina lease, a right-of-use asset of \$2.0 million and a liability of \$1.4 million were recorded on our balance sheet. Total cash paid for operating leases during the three and nine months ended September 30, 2020 was \$0.08 million and \$0.2 million and is included within cash flows from operating activities within the consolidated statement of cash flows.

The Company leases furniture and specialized lab equipment under finance leases. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset. The effective interest rate is 6.17%.

The Company's lease cost is reflected in the accompanying statements of operations and comprehensive loss as follows:

	For the Three Months Ended September 30, 2020	For the Nine Months Ended September 30, 2020
Operating lease cost	\$ 113,222	\$ 321,469
Finance lease cost		
Amortization of lease assets	29,725	84,476
Interest on lease liabilities	4,522	13,837
Total finance lease cost	\$ 34,247	\$ 98,313

The weighted average remaining lease term and incremental borrowing rate as of September 30, 2020 were as follows:

Weighted average remaining lease term	
Operating leases	6.1 years
Finance leases	2.3 years
Weighted average discount rate	
Operating leases	6.51 %
Finance leases	6.17 %

Maturities of operating and finance lease liabilities as of September 30, 2020 were as follows:

	Operating Leases	Finance Leases	Total
2020 (excluding the nine months ended September 30, 2020)	\$ 91,478	\$ 30,060	\$ 121,538
2021	369,995	120,684	490,679
2022	360,839	155,694	516,533
2023	244,973	10,284	255,257
2024	231,503	-	231,503
2025	238,452	-	238,452
Thereafter	454,820	-	454,820
Total minimum lease payments	1,992,060	316,722	2,308,782
Less: imputed interest	(346,216)	(22,432)	(368,648)
Present value of lease liabilities	<u>\$ 1,645,844</u>	<u>\$ 294,290</u>	<u>\$ 1,940,134</u>

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

2019 (excluding the nine months ended September 30, 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	<u>\$ 350,290</u>

14. Subsequent Events

Subsequent to the quarter ended September 30, 2020, the Company has issued an additional 830,667 shares of common stock in at-the-market offerings and received \$1.0 million of net proceeds from such sales.

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, 2019 filed with the Securities and Exchange Commission on March 30, 2020 (the "2019 Annual Report"). This discussion may contain forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements." You should review the disclosure under the heading "Risk Factors" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

OVERVIEW

We are a biopharmaceutical company primarily engaged in the development of immune therapies and vaccines. Our gp96 platform is designed to activate the immune system. This platform has broad applications in cancer and infectious disease. Our platform leverages gp96's role as a natural molecular warning system that presents antigens to the immune system. HS-110 (viagenpumatucl-L) is our first allogeneic ("off-the-shelf") cell line biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's T-cells to destroy cancer. HS-130 is an allogeneic cell line engineered to express the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T-cells, with the potential to augment antigen-specific CD4+ T-cell and CD8+ T-cell responses. We have initiated development of a new COVID-19 vaccine program under our Zolovax, Inc. subsidiary that utilizes our gp96 platform to secrete SARS-CoV-2 antigens. Our subsidiary Pelican Therapeutics, Inc. ("Pelican"), is developing PTX-35, a novel T-cell co-stimulator agonist antibody targeting 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, dosed twelve patients in our Phase 1 clinical trial of HS-130 and dosed five patients in our Phase 1 clinical trial of PTX-35. We are also providing pre-clinical, CMC development, and administrative support for these operations; while constantly focusing on protecting and expanding our intellectual property in areas of strategic interest. As we advance our clinical programs, we are in close contact with our CROs and clinical sites and are assessing the impact of COVID-19 on our studies and current timelines and costs.

Our Clinical Programs

In July 2019, we 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-PD1 checkpoint inhibitor nivolumab (Opdivo®) or more recently, Merck & Co., Inc.'s (Merck's) anti-PD1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®). We also announced interim results of this study in November 2019. Promising clinical activity was observed in our Phase 2 trial in NSCLC patients whose disease has progressed after prior treatment with a checkpoint inhibitor.

We continue to follow up on patients who have enrolled in our HS-110 Phase 2 trial and advance development of the Pelican assets. As a result of COVID-19, we temporarily paused enrollment in our Phase 1 clinical trial of HS-130 as we were unable to obtain the proper testing necessary for our protocol without the risk of unnecessary exposure of patients to COVID-19. We have since resumed enrollment and do not expect that this will significantly impact the overall timelines for the Phase 1 clinical trial of HS-130.

We currently do not have any products approved for sale and we have not generated any significant revenue since our inception and have not generated any revenue from product sales. We expect to continue to incur significant expenses and

to incur increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- initiate clinical trials and 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; and
- 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.

About our gp96 Platform

Our gp96 platform is designed to activate and expand tumor antigen specific “killer” T-cells to destroy a patient’s cancer. By turning immunologically “COLD tumors HOT,” we believe our platform will become an essential component of the immuno-oncology regimen to enhance the effectiveness and durability of checkpoint inhibitors and other cancer therapies, thereby improving outcomes for those patients less likely to benefit from checkpoint inhibitors alone.

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

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

An Allogenic Cell-Based Approach to Activating the Immune System

Our gp96 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.

About ComPACT®

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

About COVID-19 Program

Besides its utility in oncology, our gp96 platform has been shown to activate the human immune system to combat infectious diseases. Our collaborators have laid a solid foundation by engineering different pathogenic antigens into our platform. Previous preclinical studies using gp96 platform includes SIV/HIV, malaria and Zika. We initiated a COVID-19 vaccine program in collaboration with the University of Miami in March 2020.

During the third quarter of 2020 we commenced preclinical testing of the vaccine under a sponsored research agreement and anticipate continued development of a cell-based vaccine expressing gp96-Ig, OX40L-Ig and SARS-CoV-2 protein S during the fourth quarter of 2020. In July 2020, we announced generation of proof of concept data demonstrating vaccine immunogenicity in relevant preclinical models, including expansion of human-HLA-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein. In August 2020, we reported preclinical data for our gp96-based COVID-19 vaccine generated at the University of Miami Miller School of Medicine, showing robust T cell mediated immune response directed against the spike protein of SARS-CoV-2. Also in August 2020, we announced publication of positive preclinical COVID-19 vaccine results, that included data supporting that our gp96-based COVID-19 vaccine induces systemic and tissue-specific (lung) memory CD8+ T cells and tissue-resident memory CD8+ T cells.

The strategy for this program includes a focus on providing prophylactic protection to elderly patients and those with underlying health conditions and driving a cellular immune response via CD8+ T cells, in addition to a humoral immune response. We have submitted grant applications to fund and accelerate COVID-19 vaccine development; however, there can be no assurance that our grant application will be approved and even if approved, the amount of grant funding that we will receive.

About PTX-35

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

When combined in preclinical studies with Heat's gp96 platform immunotherapies and an anti-PD-1 checkpoint inhibitor, PTX-35 has been shown to enhance antigen specific T-cell activation to eliminate tumor cells. Pelican is also developing other biologics that target TNFRSF25 for various immunotherapy approaches, including PTX-45, an agonist of TNFRSF25 designed as a human TL1A-Ig like fusion protein.

COVID-19 Impact on our Business

The COVID-19 global pandemic may pose significant risks to our business. The public health actions being undertaken to reduce spread of the virus are and may continue to create significant disruptions with respect to patient enrollment in trials, hospital operating procedures including testing and data collection, the ability of suppliers to continue to manufacture products and the reliability of our supply chain and our ability to continue our laboratory operations. As of the date of this Form 10-Q, we have not experienced a material adverse effect on our business nor the need for a reduction in our work force and we do not expect any material impact on our long-term operations. However, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects depend on future developments which are highly uncertain and cannot be predicted, including, but not limited to, new information which may emerge concerning the increased severity of COVID-19, the actions to contain COVID-19, or treat its impact. Accordingly, management is evaluating our liquidity position, communicating with and monitoring the actions of our customers and suppliers, and reviewing our near-term financial performance as we manage through the uncertainty related to the coronavirus. If the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our clinical development timeline, which would adversely affect our business, financial condition, results of operations and growth prospects.

We have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business. As of the date of this report:

- Our employees are restricted from traveling, both in the interests of their health as well as at the request of our vendors as they seek to increase critical care capacity;
- our non-essential office-based employees have been instructed to work remotely, and
- our lab is operating under our business continuity plan with precautions including, increasing distancing and regularly monitoring temperatures.

As discussed in more detail below, we will closely monitor our liquidity and capital resources through the disruption caused by the COVID-19 pandemic.

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 2019 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, 2020 and 2019

Revenues. For the three months ended September 30, 2020 we recognized \$0.8 million of grant revenue for qualified expenditures under the CPRIT grant and NIH grant. No grant revenue was recognized under the CPRIT grant for the three months ended September 30, 2019. The increase in grant revenue in the current-year period primarily reflects the expected timing of completion of deliveries under the current phase of the contracts. As of September 30, 2020, we had deferred revenue of \$1.2 million for CPRIT proceeds received but for which the costs had not been incurred or the conditions of the award had not been met. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.

Research and development expense. Research and development expenses was \$3.2 million and \$3.1 million for the three months ended September 30, 2020 and 2019, respectively. The components of R&D expense are as follows, in millions:

	For the Three Months Ended	
	September 30,	
	2020	2019
Programs		
HS-110	\$ 0.1	\$ 0.8
HS-130	0.2	0.2
PTX-35	0.5	0.7
COVID-19	0.1	—
Other programs	0.1	0.1
Unallocated research and development expenses	2.2	1.3
	<u>\$ 3.2</u>	<u>\$ 3.1</u>

- HS-110 expense decreased \$0.7 million, reflecting the current-period mix of development activities, primarily due to decreased costs associated with the transition of patients from active treatment into long-term follow-up.
- HS-130 expense was \$0.2 million due to regulatory consulting and investigator site payments for the ongoing Phase 1 clinical trial.
- PTX-35 expense decreased \$0.2 million primarily due to decreased manufacturing costs.
- COVID-19 program was initiated in Q1 2020 and primarily represents sponsored research agreement costs.
- Other programs include preclinical costs associated with our Zika program, T-cell costimulatory programs, and laboratory supplies.
- Unallocated research expenses primarily reflects personnel costs, including stock-based compensation from stock awards.

General and administrative expense. General and administrative expense was \$6.6 million and \$2.0 million for the three months ended September 30, 2020 and 2019. The significant increase was primarily due to stock-compensation expense. On July 28, 2020, and August 24, 2020, the Company granted, as fulfillment of a contractual obligation with respect to a milestone which has been met, options to purchase an aggregate of 3,412,100 shares of common stock to the Chief Executive Officer. These options were vested and exercisable upon grant and therefore contributed \$4.3 million to the significant increase in general and administrative expense.

Change in fair value of contingent consideration. The change in fair value of contingent consideration was \$0.2 million for the three months ended September 30, 2020, compared to \$0.5 million in the three months ended September 30, 2019. The change in the 2020 period primarily reflects the re-calculation of discounted cash flows for the passage of time and milestone achievement.

Total non-operating income (loss). Total non-operating income was \$0.2 million for the three months ended September 30, 2020 compared to \$0.02 million for the three months ended September 30, 2019. Other income primarily consists of foreign currency adjustments and interest income on cash and short-term investment balances.

Net loss attributable to Heat Biologics, Inc. We had a net loss attributable to Heat Biologics, Inc. of \$8.9 million, or (\$0.06) per basic and diluted share for the quarter ended September 30, 2020 compared to a net loss of \$6.2 million, or (\$0.18) per basic and diluted share for the quarter ended September 30, 2019.

Comparison of the Nine Months Ended September 30, 2020 and 2019

Revenues. For the nine months ended September 30, 2020, we recognized \$2.3 million of grant revenue for qualified expenditures under the CPRIT grant and NIH grant. We recognized \$1.0 million of grant revenue for qualified expenditures under the CPRIT grant during the nine months ended September 30, 2019. The increase in grant revenue in the current-year period primarily reflects the expected timing of completion of deliveries under the current phase of the contracts.

Research and development expense. Research and development expenses decreased approximately 9.3% to \$8.8 million for the nine months ended September 30, 2020 compared to \$9.7 million for the nine months ended September 30, 2019. The components of R&D expense are as follows, in millions:

	For the Nine Months Ended September 30,	
	2020	2019
Programs		
HS-110	\$ 0.5	\$ 2.5
HS-130	0.6	0.3
PTX-35	1.6	2.8
COVID-19	0.2	—
Other programs	0.2	0.4
Unallocated research and development expenses	5.7	3.7
	<u>\$ 8.8</u>	<u>\$ 9.7</u>

- HS-110 expense decreased \$2.0 million, reflecting the current-period mix of development activities, primarily due to decreased costs associated with the transition of patients from active treatment into long-term follow-up.
- HS-130 expense increased \$0.3 million due to dosing of patients during the first nine months of 2020, third-party regulatory consulting and investigator site payments for the ongoing Phase 1 clinical trial.
- PTX-35 expense decreased \$1.2 million primarily due to the transition from pre-clinical development to manufacturing development and patient dosing.
- COVID-19 program was initiated in Q1 2020 and primarily represents sponsored research agreement costs.
- Other programs include preclinical costs associated with our Zika program, T-cell costimulatory programs, and laboratory supplies.
- Unallocated research expenses primarily reflects personnel costs, including stock-based compensation from stock awards.

General and administrative expense. General and administrative expense was \$11.7 million and \$7.2 million for the nine months ended September 30, 2020 and 2019. The significant increase in general and administrative expense was primarily due to stock-based compensation expense. On July 28, 2020, and August 24, 2020, the Company granted, as fulfillment of a contractual obligation with respect to a milestone which has been met, options to purchase an aggregate of 3,412,100 shares of common stock to the Chief Executive Officer. These options were vested and exercisable upon grant and therefore contributed \$4.3 million to the significant increase in general and administrative expense.

Change in fair value of contingent consideration. The change in fair value of contingent consideration was \$1.0 million for the nine months ended September 30, 2020, compared to \$0.7 million in the nine months ended September 30, 2019. The change in the 2020 period primarily reflects the re-calculation of discounted cash flows for the passage of time and milestone achievement.

Total non-operating income (loss). Total non-operating loss was (\$0.7) million for the nine months ended September 30, 2020, compared to income of \$0.3 million for the nine months ended September 30, 2019. The change of (\$1.0) million primarily consists changes in fair value related to warrants of (\$1.0) million.

Net loss attributable to Heat Biologics, Inc. We had a net loss attributable to Heat Biologics, Inc. of \$19.6 million, or (\$0.20) per basic and diluted share for the nine months ended September 30, 2020 compared to a net loss of \$16.7 million, or (\$0.50) per basic and diluted share for the nine months ended September 30, 2019.

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 of our preferred stock, common stock and debt. Since our initial public offering, we have primarily financed our operations with net proceeds from the public offering of our securities and to a lesser extent, the proceeds from the exercise of warrants. During May 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately \$18.8 million and after the closing of the offering, an additional \$4.8 million from the exercise of 3,054,667 warrants issued in this offering. During November 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately \$12.7 million. For the year ended December 31, 2018, we received net proceeds of approximately \$3.8 million from sales of our common stock in at-the-market offerings. On January 21, 2020, we closed an underwritten public offering of shares of our common stock and warrants to purchase shares of our common stock pursuant to which we received net proceeds of approximately \$6.4 million. For the nine months ended September 30, 2020, we received net proceeds of \$113.4 million from the sale of 91,399,427 shares of our common stock in at-the-market offerings. As of September 30, 2020, we had an accumulated deficit of \$124.2 million. We had net losses of \$20.4 million and \$16.6 million for the years ended December 31, 2019 and 2018, respectively. We had net losses of \$19.8 million and \$17.1 million for the nine months ended September 30, 2020 and 2019, respectively. Subsequent to the quarter ended September 30, 2020, we have issued an additional 830,667 shares of common stock in “at-the-market” offerings and received \$1.0 million of net proceeds.

We expect to incur significant expenses and continued losses from operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and advance our clinical trials of, and seek marketing approval for, our product candidates and as we add to our product candidate pipeline. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Although we currently have sufficient funds to complete our Phase 2 clinical trials, as currently planned, and expect that we will have sufficient funds to fund our operations into 2023, we will need to obtain substantial additional future funding in connection with our future planned clinical trials. While we are currently funding vaccine development and preclinical studies, we do not expect to use significant corporate resources to advance our COVID-19 program. We are applying for several large grants to support clinical development of this program and are engaged in collaboration discussions, which we believe may provide attractive and non-dilutive pathways to help accelerate development of our COVID-19 program; however, there can be no assurance that we will receive such grant funding or if received, the amount of such grant funding. Adequate

additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which include sales of our common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We will need to generate significant revenues to achieve profitability, and we may never do so. As of September 30, 2020, we had approximately \$117.3 million in cash and cash equivalents and short-term investments.

Cash Flows

Operating activities. The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities during the nine months ended September 30, 2020 was \$15.6 million compared to \$12.6 million during the same period in 2019. The increase was primarily due to an increase in net loss of \$2.7 million, non-cash changes in Goodwill impairment of \$0.7 million, prepaid expense and other current assets of \$1.4 million, and changes in deferred revenue and accounts payable of \$2.9 million, offset by an increase in non-cash stock-based compensation of \$3.1 million, increase in the fair value of warrants and contingent consideration of \$1.3 million and other net changes of \$0.3 million.

Investing activities. Net cash used in investing activities was \$87.1 million during the nine months ended September 30, 2020 compared to \$0.3 million during the same period in 2019. The increase is from the net purchase of short-term investments of \$86.8 million and lab equipment of \$0.3 million.

Financing activities. Net cash provided by financing activities was \$118.4 million during the nine months ended September 30, 2020 compared to \$0.02 million during the nine months ended September 30, 2019. The increase was primarily due to a public offering of common stock and warrants of \$6.6 million, sale of our common stock through an at-the-market Common Stock Sales Agreement with B. Riley FBR, Inc. and Cantor Fitzgerald & Co. for \$116.3 million, net of related stock issuance costs of \$3.0 million and the payment of contingent consideration of \$2.0 million.

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

Current and Future Financing Needs

We have incurred an accumulated deficit of \$124.2 million through September 30, 2020. We have incurred negative cash flows from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts.

We 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;
- the receipt of grant funding if any; and
- clinical laboratory development and testing

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our equity or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock, such as through the Amended and Restated Common Stock Sales Agreement with B. Riley FBR, Inc. and Cantor Fitzgerald & Co., or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed. While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

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, 2020. 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, 2020 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

During the three months ended September 30, 2020, 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) that occurred 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.

Investing in our securities involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and notes thereto. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. The following information updates should be read in conjunction with the information disclosed in Part 1, Item 1A, "Risk Factors," contained in our 2019 Annual Report. Except as disclosed below, there have been no material changes from the risk factors and uncertainties disclosed in our 2019 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.

We have incurred net losses in each year since our inception, including net losses of \$19.8 million and \$17.1 million for the nine months ended September 30, 2020 and 2019, respectively. We had an accumulated deficit of \$124.2 million as of September 30, 2020. 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.

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, 2020, our operating activities used net cash of approximately \$15.6 million and as of September 30, 2020, our cash and cash equivalents and short-term investments were approximately \$117.3 million. During the years ended December 31, 2019 and 2018, our operating activities used net cash of approximately \$12.8 and \$21.7 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 complete patient monitoring, post-enrollment of the Phase 2 clinical trial for HS-110, and Phase 1 clinical trials for both PTX-35 and HS-130. We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses, continue our preclinical and clinical development of our current product candidates and any potential additional product candidates. 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. 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. In the past we have received notices from the Listing Qualifications Department of Nasdaq Stock Market LLC ("Nasdaq") that we failed to comply with the stockholder's equity requirements and the minimum closing bid requirements. On June 21, 2019, we received written notice from the Listing Qualifications Department of the Nasdaq Stock Market LLC notifying us that for the preceding 30 consecutive business days (May 9, 2019 through June 20, 2019), our common stock did not maintain a minimum closing

bid price of \$1.00 per share (“Minimum Bid Price Requirement”) as required by Nasdaq Listing Rule 5550(a)(2). The notice had 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 initially had a compliance period of 180 calendar days, or until December 18, 2019, to regain compliance with Nasdaq Listing Rule 5550(a)(2), which compliance period had been extended to June 15, 2020. On April 16, 2020 Nasdaq extended the bid price compliance requirement to August 31, 2020 due to extraordinary market conditions.

At the February 27, 2020 Special Meeting of Stockholders, the stockholders approved an amendment to effect a reverse stock split of our common stock within a range of 1-for-2 and 1-for-50, at the sole discretion of the Board of Directors. On July 24, 2020, we received written notice from The Nasdaq Capital Market that from July 10, 2020 through July 23, 2020, the closing bid price of our common stock has been at \$1.00 per share or greater and accordingly we had regained compliance with Nasdaq Listing Rule 5550(a)(2) and the matter was now closed. There can be no assurance given that we will be able to continue to satisfy our continued listing requirements and maintain the listing of our common stock on The Nasdaq Capital Market going forward.

Global health crises may adversely affect our planned operations.

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

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

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

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

- delays in initiation of or difficulties in enrolling patients in our clinical trials due to a lack of personal protection equipment supply for patients and subsequent temporary cessation of non-essential patient procedures;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;

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

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

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

We face competitive and other risks in our COVID-19 vaccine program.

We have recently announced preclinical testing of a new vaccine program for treatment of certain patients with COVID-19. This SARS-CoV2 disease is extremely challenging and there are many companies addressing COVID-19, both in vaccines and therapeutic treatments, many of which have significantly greater resources and capital than we do and are further along in the clinic than we are. The competition for funding research and development in this disease, including grant funding, is intense and there can be no assurance that we will be able to obtain adequate funding to carry out our development plan or that, even if funding is obtained, our vaccine will be effective, timely, and accepted by appropriate regulatory authorities.

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

On November 5, 2020, we had 159,845,850 shares of our common stock outstanding, all of which are currently eligible for sale in the public market, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 promulgated under the Securities Act. It is conceivable that stockholders may wish to sell some or all of their shares. If our stockholders sell substantial amounts of our common stock in the public market at the same time, the market price of our common stock could decrease significantly due to an imbalance in the supply and demand of our common stock. Even if they do not actually sell the stock, the perception in the public market that our stockholders might sell significant shares of our common stock could also depress the market price of our common stock.

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

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

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not Applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not Applicable.

ITEM 5. OTHER INFORMATION.

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

<u>Exhibit No.</u>	<u>Description</u>
10.1	Amended and Resated At Market Issuance Sales Agreement, dated August 24, 2020, by and among Heat Biologics, Inc., B. Riley Securities, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 24, 2020 (File No. 001-35994).
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 9, 2020

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

Date: November 9, 2020

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

**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, 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;
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 9, 2020

By: /s/ Jeffrey Wolf

Name: Jeffrey Wolf
Title: Chief Executive Officer
(Principal Executive Officer)

**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, 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;
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 9, 2020

By: /s/ William Ostrander

Name: William Ostrander

Title: Vice President of Finance

(Principal Financial and Accounting Officer)

**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, 2020 (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 9, 2020

By: /s/ Jeffrey Wolf

Name: Jeffrey Wolf
Title: Chief Executive Officer
(Principal Executive Officer)

**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, 2020 (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 9, 2020

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