

**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, 2021**

**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 (The Nasdaq Capital Market)

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

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

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

Large accelerated filer	<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 9, 2021, there were 25,403,519 shares of Common Stock, \$0.0002 par value per share, outstanding.

HEAT BIOLOGICS, INC.

TABLE OF CONTENTS

	<u>Page No.</u>
<b><u>PART I—FINANCIAL INFORMATION</u></b>	
<a href="#">Item 1. Financial Statements</a>	2
<a href="#">Consolidated Balance Sheets as of September 30, 2021 (unaudited) and December 31, 2020</a>	2
<a href="#">Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2021 and September 30, 2020</a>	3
<a href="#">Consolidated Statements of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2021 and September 30, 2020</a>	4
<a href="#">Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2021 and September 30, 2020</a>	6
<a href="#">Notes to the Consolidated Financial Statements (unaudited)</a>	7
<a href="#">Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	23
<a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a>	32
<a href="#">Item 4. Controls and Procedures</a>	32
<b><u>PART II—OTHER INFORMATION</u></b>	
<a href="#">Item 1. Legal Proceedings</a>	32
<a href="#">Item 1A. Risk Factors</a>	33
<a href="#">Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</a>	34
<a href="#">Item 3. Defaults Upon Senior Securities</a>	35
<a href="#">Item 4. Mine Safety Disclosures</a>	35
<a href="#">Item 5. Other Information</a>	35
<a href="#">Item 6. Exhibits</a>	36
<a href="#">SIGNATURES</a>	38

---

## **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, our ability to successfully operate a manufacturing facility, 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, 2020 filed with the SEC on March 25, 2021 (the “2020 Annual Report”). Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

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

## **NOTE REGARDING COMPANY REFERENCES**

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

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

HEAT BIOLOGICS, INC.  
Consolidated Balance Sheets

	September 30, 2021 (unaudited)	December 31, 2020
<b>Current Assets</b>		
Cash and cash equivalents	\$ 7,882,412	\$ 10,931,890
Short-term investments	101,032,250	100,842,438
Accounts receivable	71,420	177,239
Prepaid expenses and other current assets	2,845,226	1,842,620
<b>Total Current Assets</b>	<u>111,831,308</u>	<u>113,794,187</u>
<b>Property and Equipment, net</b>	<u>1,766,898</u>	<u>676,262</u>
<b>Other Assets</b>		
In-process R&D	5,866,000	5,866,000
Goodwill	1,452,338	1,452,338
Grant receivable	870,032	—
Operating lease right-of-use asset	1,885,681	2,035,882
Finance lease right-of-use asset	533,561	247,194
Other assets	8,199,850	—
Deposits	249,557	122,779
<b>Total Other Assets</b>	<u>19,057,019</u>	<u>9,724,193</u>
<b>Total Assets</b>	<u>\$ 132,655,225</u>	<u>\$ 124,194,642</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,065,663	\$ 1,051,764
Deferred revenue, current portion	—	603,717
Operating lease liability, current portion	341,977	278,753
Finance lease liability, current portion	222,313	108,127
Accrued expenses and other liabilities	1,660,288	1,614,534
<b>Total Current Liabilities</b>	<u>3,290,241</u>	<u>3,656,895</u>
<b>Long Term Liabilities</b>		
Other long-term liabilities	50,511	36,243
Derivative warrant liability	30,971	33,779
Deferred tax liability	361,911	361,911
Deferred revenue, net of current portion	237,500	237,500
Operating lease liability, net of current portion	1,152,008	1,301,636
Financing lease liability, net of current portion	348,128	160,240
Contingent consideration	2,564,608	2,250,844
Contingent consideration, related party	753,907	661,671
<b>Total Liabilities</b>	<u>8,789,785</u>	<u>8,700,719</u>
Commitments and Contingencies		
<b>Stockholders' Equity</b>		
Common stock, \$.0002 par value; 250,000,000 and 250,000,000 shares authorized, 25,143,315 and 22,592,500 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	5,028	4,519
Additional paid-in capital	277,097,787	247,048,349
Accumulated deficit	(152,155,580)	(130,647,485)
Accumulated other comprehensive loss	(52,545)	(166,056)
<b>Total Stockholders' Equity - Heat Biologics, Inc.</b>	<u>124,894,690</u>	<u>116,239,327</u>
<b>Non-Controlling Interest</b>	<u>(1,029,250)</u>	<u>(745,404)</u>
<b>Total Stockholders' Equity</b>	<u>123,865,440</u>	<u>115,493,923</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 132,655,225</u>	<u>\$ 124,194,642</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,	
	2021	2020	2021	2020
<b>Revenue:</b>				
Grant and contract revenue	\$ 501,567	\$ 849,732	\$ 1,499,706	\$ 2,344,777
<b>Operating expenses:</b>				
Research and development	4,381,542	3,172,663	12,004,084	8,745,966
General and administrative	3,390,093	6,579,193	11,011,003	11,651,415
Change in fair value of contingent consideration	295,000	229,000	406,000	1,045,000
Total operating expenses	<u>8,066,635</u>	<u>9,980,856</u>	<u>23,421,087</u>	<u>21,442,381</u>
Loss from operations	<u>(7,565,068)</u>	<u>(9,131,124)</u>	<u>(21,921,381)</u>	<u>(19,097,604)</u>
Change in fair value of warrant liability	6,831	(37,230)	2,808	(1,039,303)
Investor relations expense	—	—	—	(66,767)
Interest income	195,344	140,614	567,307	249,404
Other (expense) income, net	(185,332)	111,307	(440,675)	127,599
Total non-operating income (loss)	<u>16,843</u>	<u>214,691</u>	<u>129,440</u>	<u>(729,067)</u>
Net loss before income taxes	(7,548,225)	(8,916,433)	(21,791,941)	(19,826,671)
Income tax expense	—	—	—	—
Net loss	<u>(7,548,225)</u>	<u>(8,916,433)</u>	<u>(21,791,941)</u>	<u>(19,826,671)</u>
Net loss - non-controlling interest	(115,505)	(64,824)	(283,846)	(228,526)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (7,432,720)</u>	<u>\$ (8,851,609)</u>	<u>\$ (21,508,095)</u>	<u>\$ (19,598,145)</u>
Net loss per share, basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.43)</u>	<u>\$ (0.87)</u>	<u>\$ (1.42)</u>
Weighted-average common shares outstanding, basic and diluted	25,137,628	20,532,696	24,828,438	13,783,039
<b>Comprehensive loss:</b>				
Net loss	\$ (7,548,225)	\$ (8,916,433)	\$ (21,791,941)	\$ (19,826,671)
Unrealized gain (loss) on foreign currency translation	68,582	(63,954)	113,511	(24,660)
Total comprehensive loss	<u>(7,479,643)</u>	<u>(8,980,387)</u>	<u>(21,678,430)</u>	<u>(19,851,331)</u>
Comprehensive loss attributable to non-controlling interest	(115,505)	(64,824)	(283,846)	(228,526)
Comprehensive loss - Heat Biologics, Inc.	<u>\$ (7,364,138)</u>	<u>\$ (8,915,563)</u>	<u>\$ (21,394,584)</u>	<u>\$ (19,622,805)</u>

See Notes to Consolidated Financial Statements

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

Three Months Ended September 30, 2021						
	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Non-Controlling Interest	Total Stockholders' Equity
Balance at June 30, 2021	\$ 5,027	\$ 276,225,048	\$ (144,722,860)	\$ (121,127)	\$ (913,745)	\$ 130,472,343
Issuance of common stock from vesting of restricted stock awards	1	(1)	—	—	—	—
Stock-based compensation	—	872,740	—	—	—	872,740
Other comprehensive income	—	—	—	68,582	—	68,582
Net loss	—	—	(7,432,720)	—	(115,505)	(7,548,225)
<b>Balance at September 30, 2021</b>	<b>\$ 5,028</b>	<b>\$ 277,097,787</b>	<b>\$ (152,155,580)</b>	<b>\$ (52,545)</b>	<b>\$ (1,029,250)</b>	<b>\$ 123,865,440</b>
Nine Months Ended September 30, 2021						
	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2020	\$ 4,519	\$ 247,048,349	\$ (130,647,485)	\$ (166,056)	\$ (745,404)	\$ 115,493,923
Issuance of common stock under ATM, net of issuance costs	420	26,303,862	—	—	—	26,304,282
Issuance of common stock from vesting of restricted stock awards	83	(83)	—	—	—	—
Stock issuance costs	—	(658,184)	—	—	—	(658,184)
Stock-based compensation	—	4,376,588	—	—	—	4,376,588
Issuance of restricted stock	3	(3)	—	—	—	—
Exercise of options	6	27,255	—	—	—	27,261
Cancellation and payout of fractional shares	(3)	3	—	—	—	—
Other comprehensive income	—	—	—	113,511	—	113,511
Net loss	—	—	(21,508,095)	—	(283,846)	(21,791,941)
<b>Balance at September 30, 2021</b>	<b>\$ 5,028</b>	<b>\$ 277,097,787</b>	<b>\$ (152,155,580)</b>	<b>\$ (52,545)</b>	<b>\$ (1,029,250)</b>	<b>\$ 123,865,440</b>

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

	<b>Three Months Ended September 30, 2020</b>					
	<b>Common Stock</b>	<b>APIC</b>	<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Income (Loss)</b>	<b>Non-Controlling Interest</b>	<b>Total Stockholders' Equity</b>
Balance at June 30, 2020	\$ 3,144	\$ 163,026,420	\$ (115,344,284)	\$ 28,044	\$ (577,454)	\$ 47,135,870
Issuance of common stock under ATM, net of issuance costs	1,330	79,296,779	—	—	—	79,298,109
Stock issuance costs	—	(1,984,155)	—	—	—	(1,984,155)
Stock-based compensation	—	4,728,894	—	—	—	4,728,894
Exercise of warrants	12	699,917	—	—	—	699,929
Other Comprehensive loss	—	—	—	(63,954)	—	(63,954)
Net loss	—	—	(8,851,609)	—	(64,824)	(8,916,433)
<b>Balance at September 30, 2020</b>	<b>\$ 4,486</b>	<b>\$ 245,767,855</b>	<b>\$ (124,195,893)</b>	<b>\$ (35,910)</b>	<b>\$ (642,278)</b>	<b>\$ 120,898,260</b>

  

	<b>Nine Months Ended September 30, 2020</b>					
	<b>Common Stock</b>	<b>APIC</b>	<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Loss</b>	<b>Non-Controlling Interest</b>	<b>Total Stockholders' Equity</b>
Balance at December 31, 2019	\$ 965	\$ 118,179,635	\$ (104,597,748)	\$ (11,250)	\$ (413,752)	\$ 13,157,850
January 2020 investment offering, net of underwriters discounts	571	4,105,577	—	—	—	4,106,148
Issuance of common stock under ATM, net of issuance costs	2,612	116,294,150	—	—	—	116,296,762
Issuance of common stock from vesting of restricted stock awards	47	(47)	—	—	—	—
Stock issuance costs	—	(3,076,915)	—	—	—	(3,076,915)
Stock-based compensation	—	6,050,094	—	—	—	6,050,094
Exercise of warrants	227	3,442,095	—	—	—	3,442,322
Exchange of warrants	64	773,266	—	—	—	773,330
Other comprehensive income	—	—	—	(24,660)	—	(24,660)
Net loss	—	—	(19,598,145)	—	(228,526)	(19,826,671)
<b>Balance at September 30, 2020</b>	<b>\$ 4,486</b>	<b>\$ 245,767,855</b>	<b>\$ (124,195,893)</b>	<b>\$ (35,910)</b>	<b>\$ (642,278)</b>	<b>\$ 120,898,260</b>

See Notes to Consolidated Financial Statements

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

	For the Nine Months Ended September 30,	
	2021	2020
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (21,791,941)	\$ (19,826,671)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	415,270	242,623
Noncash lease expense	63,797	73,524
Noncash interest expense	14,900	13,838
Noncash investor relations expense	—	66,767
Stock-based compensation	4,376,588	6,050,094
Change in fair value of common stock warrants	(2,808)	1,039,303
Change in fair value of contingent consideration	406,000	1,045,000
Unrealized loss (gain) on investments	278,172	(47,923)
Increase (decrease) in cash arising from changes in assets and liabilities:		
Accounts receivable	104,598	(173,447)
Prepaid expenses and other current assets	(1,029,581)	(1,199,730)
Grant receivable	(870,032)	—
Other assets	(8,199,850)	—
Accounts payable	14,766	(748,410)
Accrued expenses and other liabilities	197,428	(201,199)
Deferred revenue	(603,717)	(2,203,838)
Other long-term liabilities	14,268	26,331
Deposits	(126,778)	265,132
<b>Net Cash Used in Operating Activities</b>	<b>(26,738,920)</b>	<b>(15,578,606)</b>
<b>Cash Flows from Investing Activities</b>		
Purchase of short-term investments	(66,665,908)	(95,034,396)
Sale of short-term investments	66,197,924	8,295,222
Purchase of property and equipment	(1,383,596)	(321,301)
Proceeds from disposal of property and equipment	—	2,168
<b>Net Cash Used in Investing Activities</b>	<b>(1,851,580)</b>	<b>(87,058,307)</b>
<b>Cash Flows from Financing Activities</b>		
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	26,304,282	116,296,762
Proceeds from exercise of stock options	27,261	—
Proceeds from the exercise of warrants	—	675,675
Stock issuance costs	(658,184)	(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	(121,503)	(85,140)
<b>Net Cash Provided by Financing Activities</b>	<b>25,551,856</b>	<b>118,406,352</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>(10,834)</b>	<b>(1,243)</b>
<b>Net Change in Cash and Cash Equivalents</b>	<b>(3,049,478)</b>	<b>15,768,196</b>
<b>Cash and Cash Equivalents – Beginning of Period</b>	<b>10,931,890</b>	<b>9,039,887</b>
<b>Cash and Cash Equivalents – End of Period</b>	<b>\$ 7,882,412</b>	<b>\$ 24,808,083</b>
<b>Supplemental Disclosure for Cash Flow Information:</b>		
Right-of-use assets obtained on operating lease commencements	\$ 88,596	\$ 75,244
Right-of-use assets obtained on operating lease modifications	\$ 37,767	\$ —
Right-of-use assets obtained on financing lease commencements	\$ 408,677	\$ 173,822
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Allocation of proceeds from public offering to warrant liabilities	\$ —	\$ 2,494,823
Cashless exercise of warrants classified as liabilities	\$ —	\$ 2,766,647
Cashless exchange of warrants classified as liabilities	\$ —	\$ 773,330

See Notes to Consolidated Financial Statements

## **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, 2021 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2021.

The consolidated financial statements as of and for the three and nine months ended September 30, 2021 and 2020 are unaudited. The balance sheet as of December 31, 2020 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, 2020 filed with the SEC on March 25, 2021 (the “2020 Annual Report”).

The accompanying unaudited consolidated financial statements as of and for the three and nine months ended September 30, 2021 and 2020 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.), Scorpion Biological Services, Inc. (formerly Scorpion Biosciences, Inc), Blackhawk Bio, Inc, and Abacus Biotech, 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, 2021 and December 31, 2020, 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.

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

### ***Liquidity and Capital Resources***

The Company has an accumulated deficit of approximately \$152.2 million as of September 30, 2021 and a net loss of approximately \$7.5 million and \$21.8 million for the three and nine months ended September 30, 2021 and has not generated significant revenue or positive cash flows from operations. The Company expects to incur significant expenses and continued losses from operations for the foreseeable future. The Company expects its expenses to increase in connection with its ongoing activities, particularly as the Company continues its research and development and advances its clinical trials of, and seeks marketing approval for, its product candidates, builds its in-house bioanalytic, process development and manufacturing facility and expands its infectious disease/biological threat program. 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. Furthermore, any new business ventures that the Company may engage in are likely to require commitments of capital. Accordingly, the Company will in the future need to obtain substantial additional funding in connection with its planned 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. As of September 30, 2021, the Company had approximately \$108.9 million in cash and cash equivalents and short-term investments, which it believes is sufficient to fund its operations for at least one year from the date these consolidated financial statements were issued. This is based on the Company's current estimates, and the Company could use its available capital resources sooner than it currently expects. The Company is continually evaluating various cost-saving measures considering its cash requirements in order to focus resources on its product candidates. The Company will need to generate significant revenues to achieve profitability, and it may never do so.

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

### ***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 or its manufacturing facility, uncertainty of market acceptance of the Company's products or manufacturing capability or success of new business ventures, 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. 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 at the end of the second quarter of 2020 and no delays in overall development milestones are expected for the development of HS-130.

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

### ***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, were 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, 2021, the fair value of such warrants was \$30,971, 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, valuation of goodwill and in process research and development (“IPR&D”), income taxes, valuation of warrant liabilities, and stock-based compensation. Actual results may differ from those estimates.

### ***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, 2021.

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.

### ***Deferred Revenue***

Deferred revenue is comprised of grant funds received from an economic development grant agreement with the City of San Antonio ("Economic Development Grant") that we entered into on November 1, 2017. Under the Economic Development Grant, we received \$0.2 million in state enterprise fund grants for the purpose of defraying costs toward the purchase of laboratory equipment. As part of the agreement, we will provide the city of San Antonio with a purchase money security interest in the equipment to secure the repayment of grant funds should we fail to perform under the terms and conditions of the agreement. Our obligations under the agreement include meeting certain employment levels for a period of not less than seven years commencing on or before December 31, 2017 and establishing Pelican's corporate

headquarters in San Antonio. The Economic Development Grant funds will be recognized as income upon the achievement of the performance criteria and determination that the cash is no longer refundable to the State of Texas.

***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.

***Grants Receivable and Revenue Recognition***

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

The CPRIT grant covers the periods from June 1, 2017 through May 31, 2022, for a total grant award of up to \$15.2 million. CPRIT advances grant funds upon request by the Company consistent with the agreed upon amounts and schedules as provided in the contract. The first tranche of funding of \$1.8 million was received in May 2017, and a second tranche of funding of \$6.5 million was received in October 2017, and the third tranche of funding of \$5.4 million was received in December 2019. The remaining \$1.5 million will be awarded, on a reimbursement basis, after the Company has fulfilled every requirement of the grant and the grant has been approved to be finalized. Funds received are reflected in deferred revenue as a liability until revenue is earned. Grant revenue is recognized when qualifying costs are incurred. When grant funds are received after costs have been incurred, the Company records revenue and a corresponding grants receivable until grant funds are received.

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, 2021, the Company incurred approximately \$0.0 million and \$0.03 million of allowable expenses under the NIH grant and recognized a corresponding amount of grant revenues. For the three and nine months ended September 30, 2020, no revenue was recognized.

***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 2020 Annual Report and have not changed significantly since such filing.

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

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

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity. This ASU simplifies the accounting for convertible instruments. This ASU also requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. The ASU is effective for annual periods beginning after December 15, 2023 with early adoption permitted. We are currently evaluating the impact this standard will have on our consolidated financial statements.

## **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, the Company achieved the first milestone when it dosed the first patient in the first Phase 1 clinical trial of PTX-35.

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

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, 2021 or 2020.

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

The 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:

	September 30, 2021	December 31, 2020
Current stock price	\$ 5.95	\$ 5.36
Estimated volatility of future stock price	132.73 %	141.28 %
Risk free interest rate	0.41 %	0.17 %
Contractual term	2.16 years	2.90 years

During the year ended December 31, 2020, 470,238 warrants were exchanged for 319,756 shares of common stock. As of September 30, 2021, there were a total of 9,357 warrants outstanding that were reported as a liability on the consolidated balance sheet.

[Table of Contents](#)

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

Description	As of September 30, 2021			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Short-term investments	\$ 101,032,250	\$ 101,032,250	—	—
<b>Liabilities:</b>				
Contingent consideration	\$ 3,318,515	—	—	\$ 3,318,515
Warrant liability	\$ 30,971	—	—	\$ 30,971

Description	As of December 31, 2020			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Short-term investments	\$ 100,842,438	\$ 100,842,438	—	—
<b>Liabilities:</b>				
Contingent consideration	\$ 2,912,515	—	—	\$ 2,912,515
Warrant liability	\$ 33,779	—	—	\$ 33,779

The following table summarizes the change in fair value, as determined by Level 3 inputs, for all assets and liabilities using unobservable Level 3 inputs for the nine months ended September 30, 2021:

	Contingent Consideration	Warrant Liability
Balance at December 31, 2020	\$ 2,912,515	\$ 33,779
Change in fair value	406,000	(2,808)
Balance at September 30, 2021	\$ 3,318,515	\$ 30,971

The change in the fair value of the contingent consideration for the nine months ended September 30, 2021 was primarily due to 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, 2021 was primarily due to increase 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, 2021:

Valuation Methodology	As of September 30, 2021	
	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent Consideration	Milestone dates	2022-2031
	Discount rate	7.52
	Probability of occurrence	4.9% to 55%

The Company measures certain non-financial assets on a non-recurring basis, including goodwill and in-process R&D. 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, 2021 and December 31, 2020. Unrealized gains and losses on securities are reported in the other (expense) income line item on the statement of operations and comprehensive loss. Short-term investments at September 30, 2021 and December 31, 2020 consisted of mutual funds with fair values of \$101.0 million and \$100.8 million, respectively.

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

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

	September 30, 2021	December 31, 2020
Prepaid manufacturing expense	\$ —	\$ 316,411
Prepaid insurance	872,826	612,293
Prepaid preclinical and clinical expenses	1,748,806	690,543
Other prepaid expenses and current assets	223,594	223,373
	<u>\$ 2,845,226</u>	<u>\$ 1,842,620</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 three to eight years. Expenditures for maintenance and repairs are charged to expense as incurred.

Property and equipment consist of the following at:

	September 30, 2021	December 31, 2020
Lab equipment	\$ 2,800,198	\$ 1,607,238
Computers	85,071	71,058
Furniture and fixtures	66,106	64,523
Leasehold improvements	22,563	22,563
Construction-in-process	167,160	—
Total	3,141,098	1,765,382
Accumulated depreciation	(1,374,200)	(1,089,120)
Property and equipment, net	<u>\$ 1,766,898</u>	<u>\$ 676,262</u>

Depreciation expense was \$115,251 and \$292,960 for the three and nine months ended September 30, 2021, respectively, and \$58,853 and \$158,095 for the three and nine months ended September 30, 2020, respectively.

#### 7. Goodwill and In-Process R&D

Goodwill of \$2.2 million and in-process R&D of \$5.9 million were recorded in connection with the acquisition of Pelican, as described in Note 2. The Company performs an annual impairment test at the reporting unit level as of April 1<sup>st</sup> of each fiscal year. No impairment was recorded during the quarters ended September 30, 2021 or 2020.

## 8. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following:

	September 30, 2021	December 31, 2020
Accrued preclinical and clinical trial expenses	\$ 529,482	\$ 628,000
Accrued manufacturing expenses	174,174	175,089
Compensation and related benefits	458,914	209,600
Accrued franchise tax	147,500	172,500
Other expenses	350,218	429,345
	<u>\$ 1,660,288</u>	<u>\$ 1,614,534</u>

## 9. Stockholders' Equity

### *Underwritten Registered Offering*

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

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, 2021 to September 30, 2021 the Company sold 2,106,027 shares of common stock under the Common Stock Sales Agreement, and the Amended and Restated Common Stock Sales Agreement, at an average price of approximately \$12.18 per share, raising aggregate net proceeds of \$25,646,099 after deducting a commission up to 3%.

### *Common Stock Warrants*

As of September 30, 2021, the Company has outstanding warrants to purchase 747,383 shares of common stock issuable at a weighted-average exercise price of \$11.06 per share.

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

	Common Stock Warrants
Outstanding, December 31, 2020	758,939
Issued	31,000
Expired	(42,556)
Outstanding, September 30, 2021	<u>747,383</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 addition, at its 2021 Annual Meeting for Stockholders, the stockholders approved the Company's 2021 Subsidiaries Stock Incentive Plan (the "SSIP") which allows for the grant of equity interests in subsidiaries of the Company including Skunkworx Bio, Inc. ("SkunkWorx"), Scorpion Biological Services, Inc. ("Scorpion"), Abacus Biotech, Inc. ("Abacus"), Blackhawk Bio, Inc. ("Blackhawk") and other newly formed

subsidiaries of the Company that adopt the SSIP by resolution of their Board of Directors. On August 2, 2021 the Board of Directors, the Compensation Committee and the Board of Directors of Skunkworx, Scorpion, Abacus and Blackhawk granted to Jeff Wolf an option under the SSIP to purchase 10,526, 10,638, 10,526 and 10,526 shares of common stock of Skunkworx, Scorpion, Abacus and Blackhawk, respectively, representing beneficial ownership of approximately 5.0% of the outstanding shares of common stock of each of Skunkworx, Scorpion, Abacus and Blackhawk, respectively.

***Accounting for Stock-Based Compensation:***

***Stock Compensation Expense*** - For the three and nine months ended September 30, 2021, the Company recorded \$0.9 million and \$4.4 million of stock-based compensation expense, respectively. 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. No compensation expense of employees with stock awards was capitalized during the three and nine months ended September 30, 2021 and 2020.

***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, 2021 and 2020, the Company issued options that expire ten years from the date of grant.

***Fair Value Determination*** - The Company has used the Black-Scholes 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 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, 2021 and 2020:

- ***Volatility*** - The Company used an average historical stock price volatility of its own data plus an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms.
- ***Expected life of options*** - The expected term represents the period that the Company's stock option grants are expected to be outstanding. The Company elected to utilize the "simplified" method to estimate the expected term. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.
- ***Risk-free interest rate*** - The rate is based on U.S. Treasury interest rates at the time of the grant whose term is consistent with the expected life of the stock options.
- ***Dividend yield*** - The expected dividend yield was considered to 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. The Company accounts for forfeitures as they occur.

[Table of Contents](#)

The following table summarizes weighted-average assumptions used in our calculations of fair value for the nine months ended September 30, 2021 and 2020:

	2021	2020
Dividend yield	— %	— %
Expected volatility	102.15 %	96.26 %
Risk-free interest rate	0.67 %	0.52 %
Expected lives (years)	5.6 years	5.4 years

**Stock Option Activity** - The weighted-average fair value of options granted during the nine months ended September 30, 2021 and 2020, as determined under the Black-Scholes valuation model, was \$4.41 and \$6.30 per share, respectively.

The following is a summary of the stock option activity for the nine months ended September 30, 2021:

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Stock options outstanding at December 31, 2020	1,480,139	\$ 11.05	\$ 628,169	
Granted	604,094	5.69		
Exercised	(69,493)	6.57	\$ 32,274	
Forfeited/Expired	(124,566)	8.93		
Stock options outstanding at September 30, 2021	<u>1,890,174</u>	\$ 9.64	\$ 817,628	8.7 Years
Stock options exercisable at September 30, 2021	<u>1,089,062</u>	\$ 12.59	\$ 266,618	8.4 Years

Unrecognized compensation expense related to unvested stock options was \$2.9 million as of September 30, 2021, which is expected to be recognized over a weighted-average period of 1.4 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. 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, 2021:

	Shares	Weighted Average Fair Value
Restricted stock at December 31, 2020	239,928	\$ 4.02
Granted	432,185	5.68
Vested	(412,239)	5.16
Cancelled	—	—
Restricted stock at September 30, 2021	<u>259,874</u>	\$ 4.96

**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.

[Table of Contents](#)

The following is a summary of stock unit activity for the nine months ended September 30, 2021:

	Shares	Weighted Average Fair Value
RSUs at December 31, 2020	1,900	\$ 26.60
Vested	(1,900)	26.60
Cancelled	—	—
RSUs at September 30, 2021	—	\$ —

#### 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 through May 31, 2022. 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 on a reimbursement basis after the Company has fulfilled every requirement of the grant and the grant has been approved to be finalized.

The grant is subject to customary CPRIT funding conditions including a matching funds requirement where Pelican will match \$0.50 for every \$1.00 from CPRIT. Consequently, Pelican was 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, 2021, \$14.6 million of grant funding 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, 2021 and 2020, all of the Company's common stock options, unvested restricted stock units and warrants are anti-dilutive and therefore have been excluded from the diluted calculation.

[Table of Contents](#)

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	\$ (7,548,225)	\$ (8,916,433)	\$ (21,791,941)	\$ (19,826,671)
Net loss - Non-controlling interest	(115,505)	(64,824)	(283,846)	(228,526)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (7,432,720)</u>	<u>\$ (8,851,609)</u>	<u>\$ (21,508,095)</u>	<u>\$ (19,598,145)</u>
Weighted-average common shares outstanding, basic and diluted	<u>25,137,628</u>	<u>20,532,696</u>	<u>24,828,438</u>	<u>13,783,039</u>
Net loss per share, basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.43)</u>	<u>\$ (0.87)</u>	<u>\$ (1.42)</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, 2021 and 2020 due to their anti-dilutive effect:

	2021	2020
Outstanding stock options	1,890,174	1,308,124
Restricted stock subject to forfeiture and restricted stock units	259,874	289,316
Outstanding common stock warrants	747,383	819,866

## 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, 2021, \$1.0 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 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, 2021, and December 31, 2020, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of operations and comprehensive loss. As of September 30, 2021, and December 31, 2020, the Company had no such accruals.

At September 30, 2021, the Company has federal net operating loss carryforwards of approximately \$135,214,763, including \$3,027,284 acquired from Pelican Therapeutics, which are available to offset future taxable income.

## 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.

[Table of Contents](#)

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

In June 2021, the Company entered into a lease agreement with Durham KTP Tech 7, LLC, to lease a 15,996 square foot facility in Morrisville, North Carolina to expand its research and development activities. The lease has a term of eight years following the commencement date and provides the Company the option to extend the lease term for one five year term. It is subject to fixed rate escalation increases and also provides up to \$2.4 million for tenant improvements. As the lease had not commenced as of September 30, 2021, the Company has not recorded an operating lease ROU asset or lease liability for this lease in the accompanying condensed consolidated balance sheets. The initial estimate of the minimum amount of undiscounted lease payments due under this lease is \$4.66 million. Further, the tabular disclosure of minimum lease payments below does not include payments due under this lease.

In October 2021, Scorpion entered into a lease agreement with Merchants Ice II, LLC, to lease a 20,144 square foot facility in San Antonio, TX for general office, laboratory, research, analytical, and/or biomanufacturing purposes. Merchants Ice II, LLC is a nonprofit entity investing in the building with the intention to encourage development of emerging technologies. As a result, investments made by both Merchants Ice II, LLC and Scorpion into the building may qualify and share tax credits under the New Market Tax Credit (“NMTC”) program. Scorpion agreed that all investments and expenditures qualifying under the NMTC (i.e., certain equipment and building improvements) would be purchased by the Merchants Ice II, LLC to generate the largest possible tax incentive and Scorpion would reimburse Merchant Ice, LLC for these payments. As of September 30, 2021, and prior to the execution of the lease agreement, Scorpion has reimbursed Merchant Ice, LLC \$8.2 million which is shown in other assets on the consolidated balance sheets. Upon lease commencement, these assets will be classified as a right-of-use asset. The lease has a term of fifteen years following the commencement date and provides Scorpion the option to extend the lease term for one fifteen-year term, and one subsequent ten year term upon expiration of the first extended term. It is subject to fixed rate escalation increases and also provides up to \$2.4 million for tenant improvements. As the lease had not commenced as of September 30, 2021, Scorpion has not recorded a right-of-use asset or lease liability for this lease in the accompanying condensed consolidated balance sheets. The initial estimate of the minimum amount of undiscounted lease payments due under this lease is \$11.1 million.

Total cash paid for operating leases during the three and nine months ended September 30, 2021 was \$0.1 million and \$0.3 million respectively, 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 5.63%.

[Table of Contents](#)

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, 2021	For the Nine Months Ended September 30, 2021
Operating lease cost	\$ 121,520	\$ 348,631
Finance lease cost		
Amortization of lease assets	62,860	122,310
Interest on lease liabilities	7,812	14,900
Total finance lease cost	\$ 70,672	\$ 137,210

The weighted average remaining lease term and incremental borrowing rate as of September 30, 2021 were as follows:

Weighted average remaining lease term	
Operating leases	5.6 years
Finance leases	2.1 years
Weighted average discount rate	
Operating leases	6.44 %
Finance leases	5.63 %

Maturities of operating and finance lease liabilities as of September 30, 2021 were as follows:

	Operating Leases	Finance Leases	Total
2021 (excluding the nine months ended September 30, 2021)	\$ 105,491	\$ 61,508	\$ 166,999
2022	426,539	281,042	707,581
2023	292,921	135,631	428,552
2024	231,503	131,256	362,759
2025	238,452	-	238,452
2026	245,607	-	245,607
Thereafter	209,214	-	209,214
Total minimum lease payments	1,749,727	609,437	2,359,164
Less: imputed interest	(255,742)	(38,996)	(294,738)
Present value of lease liabilities	\$ 1,493,985	\$ 570,441	\$ 2,064,426

#### 14. Subsequent Events

The Company has evaluated its consolidated financial statements for subsequent events through November 10, 2021, the date the financial statements were available to be issued.

On October 5, 2021, Scorpion entered into a lease agreement with Merchants Ice II, LLC, to lease a 20,144 square foot facility in San Antonio, TX for general office, laboratory, research, analytical, and/or biomanufacturing purposes. The lease has a term of fifteen years following the commencement date and provides Scorpion the option to extend the lease term for one fifteen-year term, and one subsequent ten year term upon expiration of the first extended term. It is subject to fixed rate escalation increases and also provides up to \$2.36 million for tenant improvements. As the lease had not commenced as of September 30, 2021, Scorpion has not recorded a right-of-use asset or lease liability for this lease in the accompanying condensed consolidated balance sheets. The initial estimate of the minimum amount of undiscounted lease payments due under this lease is \$11.1 million.

**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, 2020 filed with the Securities and Exchange Commission on March 25, 2021 (the "2020 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 and the 2020 Annual Report 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 allogeneic vaccine platform is based on secreted gp96 and designed to activate the immune system. This platform has broad applications in cancer and infectious disease. Our platform leverages 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 fight cancer. HS-130 is another allogeneic cell line engineered to express the extracellular domain of OX40 ligand as a fusion protein (OX40L-Fc). This biologic is a key costimulator of T cells, with potential to augment antigen-specific CD4+ 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 chaperone SARS-CoV-2 antigens, eliciting an immune response against the spike glycoprotein. Our subsidiary Pelican Therapeutics, Inc. ("Pelican"), is developing PTX-35, a novel T cell co-stimulator agonist antibody targeting TNFRSF25.

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

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

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

We are also expanding our infectious disease/biothreat programs and have formed a biothreat advisory board to aid in advancing our biothreat initiatives. In addition, our Skunkworx Bio, Inc. subsidiary is utilizing advanced computational methods and bioinformatics to further enhance target precision and is developing proprietary "pocket biologics" to identify miniature proteins which bind to critical domains of druggable targets.

## **Our Clinical Programs**

We completed patient enrollment in our HS-110 Phase 2 non-small cell lung cancer (NSCLC) clinical trial and completed enrollment of patients in our HS-130 Phase 1 clinical trial that combines HS-110 with HS-130 to drive immune surveillance. Our PTX-35 safety and dose escalation Phase 1 clinical trial also continues to enroll patients. We are also providing pre-clinical, CMC development, and administrative support for these efforts; while constantly focusing on protecting and expanding our intellectual property in areas of strategic interest. We currently do not have any FDA approved products or sales and we have not generated any significant revenue since our inception nor revenue from product sales. We expect to continue to incur significant expenses and increased operating losses over the next several years. We anticipate that our expenses will increase substantially in the following areas:

- ongoing clinical trials of our product candidates;
- maintaining, expanding, and protecting our intellectual property portfolio;
- gaining regulatory approvals for our product pipeline;
- continued research and development efforts;
- the building and operation of our facility for the development of bioanalytics, process development and manufacturing activities;
- increased operational, financial, management information systems, and personnel - including personnel to support our product development and commercialization efforts; and
- expenses incurred with operating 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 can become an essential component of the immuno-oncology regimen to enhance the effectiveness and durability of checkpoint inhibitors and other cancer therapies, thereby improving outcomes for those patients less likely to benefit from checkpoint inhibitors alone.

We believe this is a highly differentiated approach as our platform delivers a broad range of tumor antigens that are previously unrecognized by the patient’s immune system. Tumor antigens are processed and chaperoned by a powerful and naturally occurring immune adjuvant, gp96, to activate an anti-cancer immune response. Our cancer vaccine therapeutics are replication incompetent, “off-the-shelf”, allogenic cell-based therapies that are locally administered into the skin. The treatment primes innate immune recognition and activates T cells to seek and destroy the cancer cells throughout the body. These gp96 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 drug biotherapeutics are fully allogeneic, “off-the-shelf” products. This provides a means to quickly administer the biotherapeutic without the need to extract and expand blood or tumor tissue from individual patients or create individualized treatment based on the patient’s haplotype. Our gp96 product candidates are produced from allogeneic cell lines expressing tumor-specific proteins common among cancers. Because each patient receives the same treatment, we believe that our immunotherapy approach offers superior speed to initiation, logistics, manufacturing efficiencies, and importantly, cost benefits, compared to “personalized” precision medicine approaches.

Our gp96 platform also delivers antigen-driven T cell activation and specific co-stimulation in a single product. The vaccine delivers both 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 in the event of cancer remission; (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).

### **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 effector cells. The key component of this innovative immunotherapy platform is the dual functionality of the gp96 heat shock protein.

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. This event 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 central role driving 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 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 our 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 first quarter of 2020, preclinical studies using a cell-based COVID-19 vaccine expressing gp96-Ig, OX40L-Ig, and the SARS-CoV-2 spike glycoprotein (ZVX-60) were started under a sponsored research agreement with the University of Miami Miller School of Medicine. In July 2020, we announced proof-of-concept data demonstrating effective vaccine immunogenicity in relevant preclinical models, including expansion of human-HLA-restricted T cells against immunodominant epitopes of SARS-CoV-2 spike glycoprotein. Data showed robust T cell mediated immune response directed against the spike protein of SARS-CoV-2. In August 2020, we announced publication of positive preclinical COVID-19 vaccine results, which included supporting data that our gp96-based COVID-19 vaccine induces systemic and tissue-specific (e.g. lung) memory CD8+ T cells and tissue-resident memory CD8+ T cells. These results were published in the peer-reviewed journal *Frontiers in Immunology* in January 2021. In January 2021, we communicated that Waisman Biomanufacturing was contracted to complete process development and manufacturing for ZVX-60. We believe this COVID-19 vaccine is especially suited for immune compromised patients and is being developed for use as either a standalone, or in combination with other vaccines, to enhance prophylactic protection against COVID-19.

The strategy for this program includes providing prophylactic protection to elderly patients and those with underlying health conditions to drive cellular immune responses via CD8+ T cells, in addition to humoral B cell immune responses. We currently plan to seek grant funding for further development of this program however to date we have not received any grant funding.

### **About PTX-35**

Pelican is focused on developing an agonist PTX-35 mAb, against a T cell costimulatory receptor, TNFRSF25. PTX-35 is designed to harness 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 biotherapeutic in cancer patients.

When combined in preclinical studies with Heat Biologics HS-110 and HS-130 immunotherapies or 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 immune biologics that target TNFRSF25 modulators for various immunotherapy approaches.

#### **Our Bioanalytics, Process Development and Manufacturing Activities**

To promote efficiency and reduce our reliance on third-party CDMO vendors, we are building in-house bioanalytic, process development, and manufacturing capabilities to support our current biotherapeutics and discovery pipeline. Manufacturing will also be offered to third parties as a fee-for-service model. We have entered into a lease for a 20,441 square foot facility in San Antonio, Texas where we plan to conduct such services and are currently in the process of building the manufacturing facility. Our expansion in Texas is part of a company-wide-growth strategy to enhance efficiency and decrease our dependence on third-party CDMO vendors as we advance our clinical trials and translate our research and development pipeline. We estimate that the investment to build out the facility with labs, equipment, and staff will be approximately \$26 million. Equipment purchases of \$8.2 million through third quarter of 2021 and approximately \$6.4 million for lab equipment expected to be spent in the fourth quarter of 2021 and first quarter of 2022 are included in the \$26 million. This excludes federal new market tax credits, historical designation federal and state tax credits, as well as city and county tax abatement incentives with the City of San Antonio and Bexar County, respectively. We intend to fund this initiative with current working capital. The potential value of tax credits and tax incentives to Scorpion are estimated at approximately \$4.5 million based on the total cost of the build out, employees hired, real property, and other factors. Operations at the facility are projected to commence by second quarter of 2022, and we expect to fill production capacity by immediately transitioning our outsourced manufacturing and development to in-house. Fee-for-service contracting will be offered to external customers after completion of the build out. However, there can be no assurance that we will be successful in these new operations. As of November 10, 2021, \$10.4 million has been spent on laboratory related manufacturing equipment for the San Antonio Facility.

#### **Recent Developments**

On August 19, 2021, we announced the formation of a biothreat advisory board comprised Andrew C. Weber, Former Assistant Secretary of Defense for Nuclear, Chemical & Biological Defense Programs; Dr. Gregory Koblentz, Associate Professor at George Mason University and leading expert on chemical and biological weapons; David Lasseter, Former Deputy Assistant Secretary of Defense for Countering Weapons of Mass Destruction, Former US Representative Jack Kingston, who also serves as the Secretariat of the Alliance for Biosecurity; and former two-term U.S. senator and Arkansas Attorney General Mark Pryor who currently serves with the law firm of Brownstein Hyatt Farber Schrek.

On October 5, 2021, Scorpion Biological Services, Inc. entered into a lease with Merchants Ice II, LLC (the “Landlord”), pursuant to which the Company will lease approximately 20,144 square feet of office and lab space located at 1305 E. Houston Street, San Antonio, Texas 78205 for general office, laboratory, research, analytical, and/or biomanufacturing purposes.

#### **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 2020 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 costs; and
- Recent accounting pronouncements.

## RESULTS OF OPERATIONS

### Comparison of the Three Months Ended September 30, 2021 and 2020

*Revenues.* For the three months ended September 30, 2021 we recognized \$0.5 million of grant revenue for qualified expenditures under the CPRIT grant. For the three months ended September 30, 2020, we recognized \$0.8 million of grant revenue for qualified expenditures under the CPRIT grant. The decrease 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, 2021, we had a grant receivable balance of \$0.9 million for CPRIT proceeds not yet received, but for which the costs had been incurred or the conditions of the award had been met. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.

*Research and development expense.* Research and development expenses increased approximately 37.5% to \$4.4 million for the three months ended September 30, 2021 compared to \$3.2 million for the three months ended September 30, 2020. The components of R&D expense are as follows, in millions:

	For the Three Months Ended September 30,	
	2021	2020
Programs		
HS-110	\$ 0.2	\$ 0.1
HS-130	0.3	0.2
PTX-35	1.1	0.5
COVID-19	0.7	0.1
Other programs	—	0.1
Unallocated research and development expenses	2.1	2.2
	<u>\$ 4.4</u>	<u>\$ 3.2</u>

- HS-110 expense was \$0.2 million, reflecting the current-period mix of development activities, primarily due to increased costs associated with our Phase 2 trial.
- HS-130 expense was \$0.3 million and included regulatory consulting and investigator site payments for the ongoing Phase 1 clinical trial.
- PTX-35 expense increased \$0.6 million primarily due to dosing of patients, third-party regulatory consulting and investigator site payments for the ongoing Phase 1 clinical trial.
- COVID-19 program was \$0.7 million and primarily represents sponsored research agreement costs and manufacturing 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 \$3.4 million and \$6.6 million for the three months ended September 30, 2021 and 2020. The decrease was due to a decrease in stock-based compensation expense of \$3.9 million due to our CEO being granted immediately vesting stock options in the third quarter of 2020 that did not recur in 2021, off-set by increased personnel costs of \$0.2 million, increase in employee travel of \$0.1 million, increase in D&O insurance of \$0.1 million, and an increase of \$0.3 million for consulting and other professional expenses to manage the business.

*Change in fair value of contingent consideration.* The change in fair value of contingent consideration was \$0.3 million for the three months ended September 30, 2021, compared to \$0.2 million for the three months ended September 30, 2020. The change in the 2021 period primarily reflects the increased timeline of the Phase 1a trial and the remeasurement of discounted cash flows for the passage of time and milestone achievement.

*Total non-operating income (loss).* Total non-operating income was \$0.02 million for the three months ended September 30, 2021 which primarily consisted of \$0.2 million of interest income, and (\$0.2) million of unrealized losses on short-term investment balances. Total non-operating income was \$0.2 million for the three months ended September 30, 2020 which primarily consisted of interest income on cash and short-term investments.

*Net loss attributable to Heat Biologics, Inc.* We had a net loss attributable to Heat Biologics, Inc. of \$7.4 million, or (\$0.30) per basic and diluted share for the three months ended September 30, 2021 compared to a net loss of \$8.9 million, or (\$0.43) per basic and diluted share for the three months ended September 30, 2020.

#### Comparison of the Nine Months Ended September 30, 2021 and 2020

*Revenues.* For the nine months ended September 30, 2021, we recognized \$1.5 million of grant revenue for qualified expenditures under the CPRIT grant and NIH grant. For the nine months ended September 30, 2020, we recognized \$2.3 million of grant revenue for qualified expenditures under the CPRIT grant. The decrease 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, 2021, we had a grant receivable balance of \$0.9 million for CPRIT proceeds not yet received but for which the costs had been incurred or the conditions of the award had been met. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.

*Research and development expense.* Research and development expenses increased approximately 36.4% to \$12.0 million for the nine months ended September 30, 2021 compared to \$8.8 million for the nine months ended September 30, 2020. The components of R&D expense are as follows, in millions:

	For the Nine Months Ended	
	September 30,	
	2021	2020
Programs		
HS-110	\$ 1.4	\$ 0.5
HS-130	0.6	0.6
PTX 35	2.2	1.6
COVID-19	1.6	0.2
Other programs	0.2	0.2
Unallocated research and development expenses	6.0	5.7
	<u>\$ 12.0</u>	<u>\$ 8.8</u>

- HS-110 expense increased \$0.9 million, reflecting the current-period mix of development activities, primarily due to increased costs associated with the transition of patients from active treatment into long-term follow-up, and increased manufacturing costs.

- HS-130 expense remained steady at \$0.6 million due to the completion of enrollment of patients, third-party regulatory consulting and investigator site payments for the ongoing Phase 1 clinical trial.
- PTX-35 expense was \$2.2 million primarily consisting of manufacturing development and patient dosing.
- COVID-19 program was \$1.6 million and primarily represents sponsored research agreement costs and manufacturing 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 \$11.0 million and \$11.7 million for the nine months ended September 30, 2021 and 2020. The decrease was primarily due to a decrease in stock-based compensation expense of \$1.7 million due to our CEO being granted immediately vesting stock options in the third quarter of 2020 that did not recur in 2021, an increase in D&O insurance premiums of \$0.3 million, an increase in consulting expenses of \$0.6 million, an increase in personnel costs of \$0.2 million, an increase in franchise taxes of \$0.2 million, and a decrease in public company expenses of \$0.3 million.

*Change in fair value of contingent consideration.* The change in fair value of contingent consideration was \$0.4 million for the nine months ended September 30, 2021, compared to \$1.0 million in the nine months ended September 30, 2020. The change in the 2021 period primarily reflects the increased timeline of the Phase 1a trial and the remeasurement of discounted cash flows for the passage of time and milestone achievement.

*Total non-operating income (loss).* Other income was \$0.1 million for the nine months ended September 30, 2021, compared to a loss of \$(0.7) million for the nine months ended September 30, 2020. The change of \$0.8 million primarily consists of a decrease in extinguishment expense and changes in fair value related to warrants of (\$1.1) million, and an increase in interest income on cash and short-term investment balances of \$0.2 million and a decrease of \$0.5 million of unrealized losses on short-term investment balances.

*Net loss attributable to Heat Biologics, Inc.* We had a net loss attributable to Heat Biologics, Inc. of \$21.5 million, or (\$0.87) per basic and diluted share for the nine months ended September 30, 2021 compared to a net loss of \$19.6 million, or (\$1.42) per basic and diluted share for the nine months ended September 30, 2020.

## **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. On January 21, 2020, we closed an underwritten public offering of shares of our common stock and warrants to purchase shares of our common stock pursuant to which we received net proceeds of approximately \$6.4 million. For the year ended December 31, 2020 we received net proceeds of approximately \$114.4 million from sales of our common stock in at-the-market offerings. For the nine months ended September 30, 2021 we received net proceeds of \$25.6 million from the sale of 2,106,027 shares of our common stock in at-the-market offerings. We had no sales of our common stock in at-the-market offerings for the three months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of \$152.2 million. We had net losses of \$26.4 million and \$20.4 million for the years ended December 31, 2020 and 2019, respectively. We had net losses of \$21.5 million and \$19.6 million for the nine months ended September 30, 2021 and 2020, respectively.

We expect to incur significant expenses and continued losses from operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and advance our clinical trials of, and seek marketing approval for, our product candidates and as we add to our product candidate pipeline including expansion of our infectious disease/biothreat programs. Our expenses will also increase due

to our recent new lease obligations for the manufacturing facility in San Antonio and related equipment expenses. 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 trial, as currently planned, and expect that we will have sufficient funds to fund our operations into 2024, we will need to obtain substantial additional future funding in connection with our future planned clinical trials, the manufacturing facility that we are building out in San Antonio, Texas and any new programs or ventures we pursue. 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, to date we have not received any grant funding for such program and 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, 2021, we had approximately \$108.9 million in cash and cash equivalents and short-term investments.

### **Cash Flows**

*Operating activities.* The use of cash during the nine months ended September 30, 2021 and 2020 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, 2021 was \$26.7 million compared to \$15.6 million during the same period in 2020. The increase was primarily due to an increased net loss of \$2.0 million, a decrease in stock-based compensation of \$1.7 million, a decrease in the change in fair value of common stock warrants of \$1.0 million, a decrease in the change in fair value of contingent consideration of \$0.6 million, a decrease in deferred revenue of \$1.6 million, an increase in other assets of \$8.2 million and an increase in accounts payable and accrued expenses of \$1.2 million. The increase in other assets relates to reimbursements made to Merchants Ice, LLC for equipment in our new San Antonio lease that will be classified as a right of use asset upon lease commencement.

*Investing activities.* Net cash used in investing activities was \$1.9 million during the nine months ended September 30, 2021 compared to \$87.1 million during the same period in 2020. The decrease is from the change in net purchases of short-term investments of \$86.3 million from 2021 to 2020 and the increase in purchases of property and equipment of \$1.1 million.

*Financing activities.* Net cash provided by financing activities was \$25.6 million during the nine months ended September 30, 2021 compared to \$118.4 million during the nine months ended September 30, 2020. The decrease of \$92.8 million was primarily due to a \$90.0 million net decrease of sales of our common stock through an at-the-market Common Stock Sales Agreement with B. Riley FBR, Inc. and Cantor Fitzgerald & Co., net of the decrease in related stock issuance costs of \$2.4 million, partially offset by a public offering of shares that occurred in 2020 of \$6.6 million.

### **Current and Future Financing Needs**

We have incurred an accumulated deficit of \$152.2 million through September 30, 2021. 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.

In order to promote efficiency and reduce our reliance on third-party vendors, we plan to enhance our in-house development of bioanalytic, process development and manufacturing capabilities and offer such services to third parties for fees. We have entered into a lease for a 20,441 square foot facility in San Antonio, TX to conduct such services and

are currently building the facility. Our proposed expansion in Texas is part of a company-wide-growth strategy to enhance efficiency and decrease our dependence on third-party vendors as we advance our clinical trials and general research and development. We estimate that the investment to build out the facility with labs, equipment, and staff will be approximately \$26 million, without taking into account federal new market tax credits based on the location in San Antonio, federal and state historical tax credits based on the historical designation of the facility, as well as city and county tax abatement incentives with the City of San Antonio and Bexar County, respectively. Equipment purchases of \$8.2 million through third quarter 2021 and approximately \$6.4 million for lab equipment expected to be spent in the fourth quarter of 2021 and first quarter of 2022 are included in the \$26 million. We intend to fund this initiative with current working capital. The potential value of tax credits and tax incentives to Scorpion are estimated to be up to approximately \$4.5 million based on the total cost of the build out, employees hired, real property, and other factors. Operations at the facility are projected to commence by second quarter of 2022, and we expect to fill production capacity by transitioning our outsourced manufacturing and development to in-house immediately and followed by contracting with external customers. However, there can be no assurance that we will be successful in these new operations. As of November 10, 2021 we have spent \$10.4 million on laboratory related manufacturing equipment for the San Antonio facility.

We intend to meet our financing needs through multiple alternatives, including, but not limited to, cash on hand, additional equity financings, debt financings and/or funding from partnerships or collaborations and potential revenue, if any, from our planned development and manufacturing facility.

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our expansion plans and cash needs of any new projects such as our planned development and manufacturing facility described above;
- the cost we incur to build the facility for the development of bioanalytics, process development and manufacturing activities, the cost of the equipment required for such facility and the revenue derived from such facility
- 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 Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. 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, 2021 our Chief Executive Officer and Chief Financial Officer 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, 2021, 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 2020 Annual Report. Except as disclosed below, there have been no material changes from the risk factors and uncertainties disclosed in our 2020 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 \$21.8 million and \$19.8 million for the nine months ended September 30, 2021 and 2020, respectively. We had an accumulated deficit of \$152.2 million as of September 30, 2021. For the years ended December 31, 2020 and 2019, we incurred a net loss of \$26.4 million and \$20.4 million, respectively. We expect to continue to incur operating losses until such time, if ever, as we are able to achieve sufficient levels of revenue from operations. Our ability to achieve profitability will depend on us obtaining regulatory approval for our product candidates and market acceptance of our product offerings and our capacity to develop, introduce and sell our products to our targeted markets. There can be no assurance that any of our product candidates will be approved for commercial sale, or even if our product candidates are approved for commercial sale that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

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

- continue to undertake preclinical development and conduct clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure;
- build a facility for the development of bioanalytics, process development and manufacturing activities; 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 may need to raise additional capital to support our long-term business plans and our failure to obtain funding when needed may force us to delay, reduce or eliminate our development programs or commercialization efforts.***

During the nine months ended September 30, 2021, our operating activities used net cash of approximately \$26.7 million and as of September 30, 2021, our cash and cash equivalents and short-term investments were approximately \$108.9 million. During the years ended December 31, 2020 and 2019, our operating activities used net cash of approximately \$22.0 million and \$12.8 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 to incur additional operating losses in the future and therefore expect our cumulative losses to increase. We do not expect to derive revenue from any of our product candidates in the near future until we or our potential partners successfully commercialize our products or we generate revenue from our manufacturing services that we plan to provide third parties. 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. In addition, we expect our expenses to increase due to the build out of the manufacturing facility in San Antonio and the purchase of equipment for the facility. 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

We will need to raise additional capital to fund our long term operations and milestone payments and we cannot be certain that funding will be available to us on acceptable terms on a timely basis, or at all. To meet our financing needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which we expect will include sales of common stock through at the market issuances, debt financings and/or funding from partnerships or collaborations. Our ability to raise capital through the sale of securities may be limited by our number of authorized shares of common stock and various rules of the SEC and the 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.

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

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

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

On November 9, 2021, we had 25,403,519 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.**

There were no sales of unregistered securities during the quarter ended September 30, 2021 that were not previously disclosed.

**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**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">3.1</a>	<a href="#">Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. dated as of March 20, 2013 (incorporated by reference to Exhibit 3.5 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)).</a>
<a href="#">3.2</a>	<a href="#">Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. dated as of May 29, 2013 filed on May 30, 2013 (incorporated by reference to Exhibit 3.6 to the Registration Statement on Form S-1/A with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365)).</a>
<a href="#">3.3</a>	<a href="#">Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. dated as of July 13, 2017 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K/A filed with the Securities and Exchange Commission on July 17, 2017 (File No. 001-35994)).</a>
<a href="#">3.4</a>	<a href="#">Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. dated as of January 18, 2018 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 19, 2018 (File No. 001-35994)).</a>
<a href="#">3.5</a>	<a href="#">Amended and Restated Bylaws, dated October 17, 2019 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 18, 2019 (File No. 001-35994)).</a>
<a href="#">3.6</a>	<a href="#">Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. dated as of March 20, 2020 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on March 23, 2020 (File No. 001-35994)).</a>
<a href="#">3.7</a>	<a href="#">Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. dated as of December 11, 2020 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File no. 001-35994)).</a>
<a href="#">10.1#</a>	<a href="#">2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit A to the Definitive Proxy Statement filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994)).</a>
<a href="#">10.2#</a>	<a href="#">2021 Subsidiaries Stock Incentive Plan (incorporated by reference to Exhibit B to the Definitive Proxy Statement filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994)).</a>
<a href="#">10.3#</a>	<a href="#">Form of Stock Option Agreement for the Heat Biologics 2021 Subsidiaries Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994)).</a>
<a href="#">10.4#</a>	<a href="#">Form of Restricted Stock Purchase Agreement for the Heat Biologics 2021 Subsidiaries Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994)).</a>
<a href="#">10.5</a>	<a href="#">Lease between Merchants Ice II, LLC and Heat Biologics, Inc. dated October 5, 2021 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 7, 2021 (File No. 001-35994)).</a>
<a href="#">31.1*</a>	<a href="#">Certification of Jeffrey Wolf, Principal Executive Officer, pursuant to Rule 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.</a>
<a href="#">31.2*</a>	<a href="#">Certification of William Ostrander, Principal Financial Officer and Principal Accounting Officer, pursuant to Rule 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.</a>
<a href="#">32.1*</a>	<a href="#">Certification of Jeffrey Wolf, Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>

[Table of Contents](#)

<a href="#">32.2*</a>	<a href="#">Certification of William Ostrander, Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

---

\* Filed herewith.

# Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.

**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 10, 2021

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

Date: November 10, 2021

By: /s/ William Ostrander  
William Ostrander  
*Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

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

I, Jeffrey Wolf, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Heat Biologics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 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 10, 2021

By: /s/ Jeffrey Wolf

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

---

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

I, William Ostrander, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Heat Biologics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 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 10, 2021

By: /s/ William Ostrander

Name: William Ostrander

Title: Chief Financial Officer

(Principal Financial Officer and Principal 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**

I, Jeffrey Wolf, Chief Executive Officer (Principal Executive Officer) of Heat Biologics, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021 (the "Form 10-Q") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented.

Date: November 10, 2021

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**

I, William Ostrander, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) of Heat Biologics, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021 (the "Form 10-Q") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented.

Date: November 10, 2021

By: /s/ William Ostrander

Name: William Ostrander

Title: Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

---