

HEAT BIOLOGICS, INC.  
Form 10-Q  
October 30, 2015

**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, 2015**

**OR**

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

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

**Heat Biologics, Inc.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

**26-2844103**

*(State or other jurisdiction of*

*I.R.S. Employer*

*Incorporation or Organization)*

*Identification No.)*

**801 Capitola Drive**

**Durham, NC**

**27713**

*(Address of principal executive offices)*

*(Zip Code)*

**(919) 240-7133**

*(Registrant's telephone number, including area code)*

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

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

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

(Do not check if smaller reporting company)

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 October 30, 2015 there were 8,415,434 shares of Common Stock, \$0.0002 par value per share, outstanding.

**HEAT BIOLOGICS, INC.**

**TABLE OF CONTENTS**

|   | <b>Page No.</b> |
|---|-----------------|
| <b>PART I—FINANCIAL INFORMATION</b>   |                 |
| <u>Item 1.</u> <u>Financial Statements</u>  | 1               |
| <u>Consolidated Balance Sheets as of September 30, 2015 (unaudited) and December 31, 2014</u>   | 1               |
| <u>Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2015 and 2014</u> | 2               |
| <u>Consolidated Statement of Stockholders Equity (unaudited) for the nine months ended September 30, 2015</u>                                   | 3               |
| <u>Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2015 and September 30, 2014</u>                    | 4               |
| <u>Notes to Consolidated Financial Statements (unaudited)</u>   | 5               |
| <u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                                     | 13              |
| <u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>  | 18              |
| <u>Item 4.</u> <u>Controls and Procedures</u>   | 18              |
| <b>PART II OTHER INFORMATION</b>  |                 |
| <u>Item 1.</u> <u>Legal Proceedings</u>   | 19              |
| <u>Item 1A.</u> <u>Risk Factors</u>   | 19              |
| <u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>   | 21              |
| <u>Item 3.</u> <u>Defaults Upon Senior Securities</u>   | 21              |
| <u>Item 4.</u> <u>Mine Safety Disclosures</u>   | 21              |
| <u>Item 5.</u> <u>Other Information</u>   | 22              |
| <u>Item 6.</u> <u>Exhibits</u>  | 22              |



## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are not guarantees of future performance and our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, our ability to raise additional capital to support our clinical development program and other operations, our ability to develop products of commercial value and to identify, discover and obtain rights to additional potential product candidates, our ability to protect and maintain our intellectual property and the ability of our licensors to obtain and maintain patent protection for the technology or products that we license from them, the outcome of research and development activities, our reliance on third-parties, competitive developments, the effect of current and future legislation and regulation and regulatory actions, as well as other risks described more fully in this Quarterly Report on Form 10-Q.

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.

## PART I FINANCIAL INFORMATION

## ITEM 1.

## FINANCIAL STATEMENTS

## HEAT BIOLOGICS, INC.

## Consolidated Balance Sheets

|   | September 30,        |           | December 31,      |
|---|----------------------|-----------|-------------------|
|   | 2015                 |           | 2014              |
|   | (unaudited)          |           |                   |
| <b>Assets</b>                                       |                      |           |                   |
| <b>Current Assets</b>                               |                      |           |                   |
| Cash and cash equivalents                           | \$ 8,210,938         | \$        | 3,714,304         |
| Investments, held to maturity (net)                 | 6,742,987            |           | 10,698,982        |
| Prepaid expenses and other current assets           | 986,264              |           | 863,227           |
| <b>Total Current Assets</b>                         | <b>15,940,189</b>    |           | <b>15,276,513</b> |
| <b>Property and Equipment, net</b>                  | <b>467,999</b>       |           | <b>445,534</b>    |
| <b>Other Assets</b>                                 |                      |           |                   |
| Restricted cash                                     | 101,146              |           | 101,129           |
| Deposits  | 69,798               |           | 19,798            |
| Related party receivable                            | 58,017               |           | 48,642            |
| Deferred financing costs, net                       | 25,379               |           | 24,554            |
| <b>Total Other Assets</b>                           | <b>254,340</b>       |           | <b>194,123</b>    |
| <b>Total Assets</b>                                 | <b>\$ 16,662,528</b> | <b>\$</b> | <b>15,916,170</b> |
| <b>Liabilities and Stockholders' Equity</b>         |                      |           |                   |
| <b>Current Liabilities</b>                          |                      |           |                   |
| Accounts payable                                    | \$ 936,361           | \$        | 1,367,426         |
| Accrued expenses and other payables                 | 2,074,174            |           | 805,968           |
| Current portion of long term debt                   | 2,053,859            |           | 397,465           |
| <b>Total Current Liabilities</b>                    | <b>5,064,394</b>     |           | <b>2,570,859</b>  |
| <b>Long Term Liabilities</b>                        |                      |           |                   |
| Long term debt, net of discount and current portion | 2,831,787            |           | 2,314,124         |
| Other long term liabilities                         | 12,228               |           |                   |
| <b>Total Liabilities</b>                            | <b>7,908,409</b>     |           | <b>4,884,983</b>  |

Commitments and Contingencies

**Stockholders' Equity**

Common stock, \$.0002 par value; 50,000,000 shares authorized,  
8,415,434 and 6,492,622 shares issued and outstanding at September  
30, 2015 (unaudited) and December 31, 2014, respectively

|   |                          |                          |
|---|--------------------------|--------------------------|
|   | 1,365                    | 982                      |
| Additional paid in capital                                      | 48,038,935               | 35,894,823               |
| Accumulated deficit   | (37,943,582)             | (24,135,447)             |
| Accumulated other comprehensive loss                            | (64,238)                 |                          |
| <b>Total Stockholders' Equity Less Non-Controlling Interest</b> | <b>10,032,480</b>        | <b>11,760,358</b>        |
| <b>Non-Controlling Interest</b>                                 | <b>(1,278,361)</b>       | <b>(729,171)</b>         |
| <b>Total Stockholders' Equity</b>                               | <b>8,754,119</b>         | <b>11,031,187</b>        |
| <br><b>Total Liabilities and Stockholders' Equity</b>           | <br><b>\$ 16,662,528</b> | <br><b>\$ 15,916,170</b> |

See Notes to Consolidated Financial Statements

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

|  | <b>Three Months Ended,<br/>September 30,</b> |                | <b>Nine Months Ended,<br/>September 30,</b> |                |
|--|--|----------------|---|----------------|
|  | <b>2015</b>                                  | <b>2014</b>    | <b>2015</b>                                 | <b>2014</b>    |
| Operating expenses:  |  |                |   |                |
| Research and development   | \$ 677,151                                   | \$ 1,025,442   | \$ 1,767,942                                | \$ 2,425,404   |
| Clinical and regulatory  | 3,718,902                                    | 1,258,566      | 9,261,529                                   | 3,218,137      |
| General and administrative   | 947,392                                      | 832,101        | 3,150,394                                   | 2,844,883      |
| Total operating expenses   | 5,343,445                                    | 3,116,109      | 14,179,865                                  | 8,488,424      |
| Loss from operations   | (5,343,445)                                  | (3,116,109)    | (14,179,865)                                | (8,488,424)    |
| Non-operating (expenses)<br>income   |  |                |   |                |
| Interest income  | 20,121                                       | 9,740          | 49,970                                      | 27,261         |
| Other income (expense)   | 4,449  | (12,762)       | 29,909                                      | (39,291)       |
| Interest expense   | (108,834)                                    | (8,138)        | (257,339)                                   | (8,138)        |
| Total non-operating<br>(expenses) income   | (84,264)                                     | (11,160)       | (177,460)                                   | (20,168)       |
| Net loss   | (5,427,709)                                  | (3,127,269)    | (14,357,325)                                | (8,508,592)    |
| Net loss non-controlling<br>interest   | (242,244)                                    | (126,865)      | (549,190)                                   | (330,675)      |
| Net loss attributable to Heat<br>Biologics, Inc.   | \$ (5,185,465)                               | \$ (3,000,404) | \$ (13,808,135)                             | \$ (8,177,917) |
| Net loss per share<br>attributable to Heat<br>Biologics, Inc. basic and<br>diluted   | \$ (0.62)                                    | \$ (0.46)      | \$ (1.75)                                   | \$ (1.27)      |
| Weighted-average number<br>of common shares used in<br>net loss per share<br>attributable to common<br>stockholders basic and<br>diluted | 8,408,376                                    | 6,469,272      | 7,880,637                                   | 6,445,129      |
| Other comprehensive loss:<br>Net loss  | (5,427,709)                                  | (3,127,269)    | (14,357,325)                                | (8,508,592)    |



|   |                |                |                 |                |
|---|----------------|----------------|-----------------|----------------|
| Unrealized loss on foreign<br>currency translation                | (27,244)       |                | (64,238)        |                |
| Total other comprehensive<br>loss                                 | (5,454,953)    | (3,127,269)    | (14,421,563)    | (8,508,592)    |
| Comprehensive loss<br>attributable to<br>non-controlling interest | (242,244)      | (126,865)      | (549,190)       | (330,675)      |
| Comprehensive loss  | \$ (5,212,709) | \$ (3,000,404) | \$ (13,872,373) | \$ (8,177,917) |

See Notes to Consolidated Financial Statements

## HEAT BIOLOGICS INC.

## Consolidated Statements of Stockholders Equity

(unaudited)

|  | Common<br>Stock | APIC          | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Loss | Non-Controlling<br>Interest | Total<br>Stockholders<br>Equity |
|--|-----------------|---------------|------------------------|---|-----------------------------|---------------------------------|
| <b>Balance at<br/>December 31,<br/>2014</b>  | \$ 982          | \$ 35,894,823 | \$ (24,135,447)        | \$  | \$ (729,171)                | \$ 11,031,187                   |
| March 2015<br>public offering,<br>1,886,000<br>shares, net of<br>underwriters<br>discounts | 377             | 11,400,493    |                        |   |                             | 11,400,870                      |
| Cashless<br>exercise of<br>options, 6,812<br>shares  |                 |               |                        |   |                             |                                 |
| Vesting of<br>restricted stock,<br>30,000 shares   | 6               | (6)           |                        |   |                             |                                 |
| Stock based<br>compensation  |                 | 1,046,086     |                        |   |                             | 1,046,086                       |
| Stock issuance<br>costs  |                 | (302,461)     |                        |   |                             | (302,461)                       |
| Accumulated<br>other<br>comprehensive<br>loss  |                 |               |                        | (64,238)                                      |                             | (64,238)                        |
| Net loss   |                 |               | (13,808,135)           |   | (549,190)                   | (14,357,325)                    |
| <b>Balance at<br/>September 30,<br/>2015</b>   | \$ 1,365        | \$ 48,038,935 | \$ (37,943,582)        | \$ (64,238)                                   | \$ (1,278,361)              | \$ 8,754,119                    |

See Notes to Consolidated Financial Statements

3

---

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

|   | <b>Nine Months Ended<br/>September 30,</b> |                    |
|---|--|--------------------|
|   | <b>2015</b>                                | <b>2014</b>        |
| <b>Cash Flows from Operating Activities</b>                                 |  |                    |
| Net loss  | \$ (14,357,325)                            | \$ (8,508,592)     |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |                    |
| Depreciation  | 84,373                                     | 41,850             |
| Amortization of debt issuance costs   | 75,818                                     | 13,848             |
| Amortization of bond premium  | 102,618                                    | 137,897            |
| Re-measurement of fair value of stock warrants liability                    |  | 7,263              |
| Stock-based compensation  | 1,046,086                                  | 722,358            |
| Increase (decrease) in cash arising from changes in assets and liabilities: |  |                    |
| Related party receivable  | (9,375)                                    | (18,446)           |
| Prepaid expenses, and other current assets, and restricted cash             | (157,440)                                  | 318,275            |
| Deposits  | (50,000)                                   | (10,478)           |
| Accounts payable  | (385,161)                                  | 28,561             |
| Accrued expenses and other payables   | 1,260,355                                  | (56,888)           |
| Other long term liabilities   | 12,228                                     |                    |
| Accrued interest  |  | (25,364)           |
| <b>Net Cash Used in Operating Activities</b>                                | <b>(12,377,823)</b>                        | <b>(7,349,716)</b> |
| <b>Cash Flows from Investing Activities</b>                                 |  |                    |
| Proceeds from maturities of short term investments                          | 14,943,468                                 | 13,827,773         |
| Purchases of short term investments   | (11,090,091)                               | (8,783,623)        |
| Purchases of property and equipment   | (106,838)                                  | (452,444)          |
| <b>Net Cash Provided by Investing Activities</b>                            | <b>3,746,539</b>                           | <b>4,591,706</b>   |
| <b>Cash Flows from Financing Activities</b>                                 |  |                    |
| Proceeds from March 2015 public offering, net of underwriting discounts     | 11,400,870                                 |                    |
| Proceeds from the exercise of stock options                                 |  | 37,719             |
| Proceeds from issuance of long term debt                                    | 2,242,575                                  | 1,435,283          |
| Payments on long term debt  | (145,161)                                  |                    |
| Stock issuance costs  | (302,461)                                  |                    |
| <b>Net Cash Provided by Financing Activities</b>                            | <b>13,195,823</b>                          | <b>1,473,002</b>   |

|   |    |           |              |
|---|----|-----------|--------------|
| <b>Effect of exchange rate changes on cash and cash equivalents</b> |    | (67,905)  |              |
| <b>Net Increase in Cash and Cash Equivalents</b>                    |    | 4,496,634 | (1,285,008)  |
| <b>Cash and Cash Equivalents Beginning of Period</b>                |    | 3,714,304 | 4,566,992    |
| <b>Cash and Cash Equivalents End of Period</b>                      | \$ | 8,210,938 | \$ 3,281,984 |
| <b>Supplemental Disclosure for Cash Flow Information</b>            |    |           |              |
| Interest paid   | \$ | 257,339   | \$ 8,138     |
| Cashless exercise of stock warrants                                 | \$ |           | \$ 452,874   |

See Notes to Consolidated Financial Statements

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

**1. Summary of Significant Accounting Policies**

*Basis of Presentation and Principles of Consolidation*

The accompanying unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial reporting. However, certain information or footnote disclosures normally included in complete financial statements prepared in accordance with U.S. GAAP have been condensed, or omitted, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). In the opinion of the Company's management, the unaudited consolidated financial statements in this Quarterly Report on Form 10-Q include all normal and recurring adjustments necessary for the fair statement of the results for the interim periods presented. The results for the three months and nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2015.

The consolidated financial statements as of and for the three and nine months ended September 30, 2015 and 2014 included in this Quarterly Report on Form 10-Q are unaudited. The balance sheet as of December 31, 2014 is derived from the audited consolidated financial statements as of that date. The accompanying unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes, together with Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on March 27, 2015 (the "2014 Annual Report").

The accompanying consolidated financial statements as of and for the three and nine months ended September 30, 2015 and 2014 include the accounts of Heat Biologics, Inc. and its subsidiaries, Heat Biologics I, Inc. ("Heat I"), Heat Biologics III, Inc. ("Heat III"), Heat Biologics IV, Inc. ("Heat IV"), Heat Biologics GmbH and Heat Biologics Australia Pty Ltd. The functional currency of the entities located outside the United States of America (the foreign entities) is the applicable local currency. Assets and liabilities of the foreign entities are translated at period-end exchange rates. Statement of operations accounts are translated at the average exchange rate during the period. The effects of foreign currency translation adjustments are included in other comprehensive loss, which is a component of accumulated other comprehensive loss in stockholders' equity. All significant intercompany accounts and transactions have been eliminated in consolidation. At December 31, 2014 and September 30, 2015, Heat Biologics, Inc. held a 92.5%

controlling interest in Heat I and accounts for its less than 100% interest in the consolidated financial statements in accordance with U.S. GAAP. Accordingly, the Company presents non-controlling interests as a component of stockholders' equity on its consolidated balance sheets and reports non-controlling interest net loss under the heading "net loss - non-controlling interest" in the consolidated statements of operations and comprehensive loss.

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company has accumulated a deficit of approximately \$37.9 million as of September 30, 2015 and a net loss of approximately \$14.4 million for the nine months ended September 30, 2015, and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. There can be no assurance that the Company will be able to complete any such transactions on acceptable terms or otherwise. If the Company is unable to obtain the necessary capital, it will need to pursue a plan to scale back its operations, license or sell its assets, seek to be acquired by another entity and/or cease operations.

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

In April 2015, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) ASU 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* ( ASU 2015-03 ). ASU 2015-03 revises Subtopic 835-30 to require that debt issuance costs be reported in the balance sheet as a direct deduction from the face amount of the related liability, consistent with the presentation of debt discounts. Prior to the amendments, debt issuance costs were presented as a deferred charge (i.e., an asset) on the balance sheet. The ASU provides examples illustrating the balance sheet presentation of notes net of their related discounts and debt issuance costs. Further, the amendments require the amortization of debt issuance costs to be reported as interest expense. Similarly, debt issuance costs and any discount or premium are considered in the aggregate when determining the effective interest rate on the debt. The amendments are effective for public business entities for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The amendments are effective for all other entities for fiscal years beginning after December 15, 2015, and interim periods within fiscal years beginning after December 15, 2016. The amendments must be applied retrospectively. All entities have the option of adopting the new requirements as of an earlier date for financial statements that have not been previously issued. The Company does not expect this ASU to have a material impact on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ( ASU 2014-15 ). The amendments in ASU 2014-15 are intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Under U.S. GAAP, financial statements are prepared under the presumption that the reporting organization will continue to operate as a going concern, except in limited circumstances. The going concern basis of accounting is critical to financial reporting because it establishes the fundamental basis for measuring and classifying assets and liabilities. Currently, U.S. GAAP lacks guidance about management's responsibility to evaluate whether there is substantial doubt about the organization's ability to continue as a going concern or to provide related footnote disclosures. This ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. This update is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company does not expect this ASU to have a significant impact on its consolidated financial statements.

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

The carrying amount of certain of the Company's financial instruments, including cash and cash equivalents, restricted cash, accounts payable and accrued expenses and other payables approximate fair value due to their short maturities. The carrying value of debt approximates fair value because the interest rate under the obligation approximates market



rates of interest available to the Company for similar instruments.

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 majority of the Company's cash equivalents and investments are classified within Level II of the fair value hierarchy.

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

**3. Investments**

Investments in certain securities may be classified into three categories:

*Held-to-maturity* - Debt securities that the Company has the positive intent and ability to hold to maturity are reported at amortized cost.

*Trading securities* - Debt and equity securities that are bought and held principally for the purpose of selling in the near term are reported at fair value with unrealized gains and losses included in earnings.

*Available-for-sale* - Debt and equity securities not classified as either securities held-to-maturity or trading securities are reported at fair value with unrealized gains or losses excluded from earnings and reported as a separate component of stockholders' equity.

The Company reassesses the appropriateness of the classification of its investments at the end of each reporting period. The Company has determined that its debt securities should be classified as held-to-maturity as of September 30, 2015 and December 31, 2014. This classification was based upon management's determination that it has the positive intent and ability to hold the securities until their maturity dates, as the underlying cash invested in these securities is not required for current operations. Investments consist of short-term FDIC insured certificates of deposit, tri-party repurchase agreement (repo) collateralized by U.S. Treasuries and agencies, and corporate notes and bonds rated A and above carried at amortized cost using the effective interest method.

Edgar Filing: HEAT BIOLOGICS, INC. - Form 10-Q

The following table summarizes information about short term investments at December 31, 2014 and September 30, 2015, respectively:

|  | <b>Amortized<br/>Cost</b> |    | <b>Gross<br/>Unrealized<br/>(Losses)</b> |    | <b>Estimated<br/>Fair Value</b> |
|--|---------------------------|----|--|----|---------------------------------|
| <b>December 31, 2014</b>   |                           |    |  |    |                                 |
| Certificates of deposit, corporate notes and bonds                                 | \$ 10,698,982             | \$ | (2,209)                                  | \$ | 10,696,773                      |
| <b>September 30, 2015</b>  |                           |    |  |    |                                 |
| Certificates of deposit, tri-party repurchase agreement, corporate notes and bonds | \$ 6,742,987              | \$ | (2,814)                                  | \$ | 6,740,173                       |

As of September 30, 2015, the estimated fair value of the investments was less than the amortized cost. Because management has the positive intention and ability to hold the investments until their maturity dates, these unrealized losses were not recorded in the accompanying unaudited consolidated financial statements.

The maturities of held-to-maturity investments at September 30, 2015 were as follows:

|  |    | <b>Less than<br/>1 Year</b> |    | <b>Total</b> |
|--|----|-----------------------------|----|--------------|
| Certificates of deposit, tri-party repurchase agreement, corporate notes and bonds | \$ | 6,742,987                   | \$ | 6,742,987    |

**HEAT BIOLOGICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

**4. Property and Equipment**

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

Property and equipment consisted of the following:

|                             | <b>September 30,</b> |    | <b>December 31,</b> |
|-----------------------------|----------------------|----|---------------------|
|                             | <b>2015</b>          |    | <b>2014</b>         |
| Furniture and fixtures      | \$ 55,275            | \$ | 50,391              |
| Computers                   | 32,485               |    | 24,174              |
| Lab equipment               | 541,066              |    | 447,423             |
| Total                       | 628,826              |    | 521,988             |
| Accumulated depreciation    | (160,827)            |    | (76,454)            |
| Property and equipment, net | \$ 467,999           | \$ | 445,534             |

Depreciation expense was \$30,436 and \$22,952 for the three months ended September 30, 2015 and 2014, respectively. Depreciation expense was \$84,373 and \$41,850 for the nine months ended September 30, 2015 and 2014, respectively.

**5. Accrued Expenses and other payables**

Accrued expenses and other payables consisted of the following:

| <b>September 30,</b> | <b>December 31,</b> |
|----------------------|---------------------|
| <b>2015</b>          | <b>2014</b>         |

|                                    |    |           |    |         |
|------------------------------------|----|-----------|----|---------|
| Patent fees                        | \$ | 35,000    | \$ | 40,000  |
| Deferred rent                      |    | 54,957    |    | 51,155  |
| Compensation and related benefits  |    | 92,233    |    | 519,092 |
| Accrued professional services fees |    | 836,333   |    |         |
| Accrued clinical trial expense     |    | 1,055,651 |    | 195,721 |
|                                    | \$ | 2,074,174 | \$ | 805,968 |

## 6. Debt Issuance Costs

During 2014, the Company recorded \$323,021 to debt discount for the initial fair value of the warrant to purchase common stock and \$27,500 to deferred financing costs related to third party fees paid in connection with the Square 1 Bank loan, which are amortized on a straight-line basis over the 42 month term of the loan which approximates the effective interest method. During the nine months ended September 30, 2015, deferred financing costs increased \$7,425 to reflect the fees related to the third tranche of the Square 1 loan, which is further discussed in footnote 7.

Total amortization expense for the debt issuance costs was \$75,818 and \$13,848 during the nine months ended September, 2015 and 2014, respectively.

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

**7. Notes Payable**

*Square 1 Bank Loan*

In August 2014, the Company entered into a secured loan with Square 1 Bank ( Loan ). The Loan provides the Company with a term loan in the aggregate principal amount not to exceed \$7,500,000 to be used to supplement working capital. The Loan is available to the Company in four tranches: \$1,500,000 was made available to the Company on August 22, 2014 ( Tranche 1 Loan ), \$1,500,000 was made available to the Company upon its enrollment of its first patient in its Phase 2 clinical trial for HS-110 ( Tranche 2 Loan ), \$2,250,000 was made available to the Company upon the initiation of the Phase 1B trial for lung cancer indication on June 30, 2015 ( Tranche 3 Loan ) and \$2,250,000 will be available to the Company upon Square 1 Bank's receipt on or before December 31, 2015 of evidence satisfactory to it of the full enrollment of our Phase 1/2 clinical trial for HS-410 ( Tranche 4 Loan ). As of September 30, 2015, the Company had drawn down \$1,500,000 under each of the Tranche 1 Loan and Tranche 2 Loan, and \$2,250,000 under the Tranche 3 Loan for a total of \$5,250,000. The Company met the milestone for Tranche 4 in October 2015 and intends to draw down on this tranche by the end of the year.

The Loan accrues interest monthly at an interest rate at the greater of prime rate plus 3.05% or 6.30% per annum. The Tranche 1 Loan was payable as interest-only until June 30, 2015 and thereafter is payable in monthly installments of principal plus accrued interest until February 22, 2018. The Tranche 2 Loan is payable as interest-only prior to October 31, 2015 and thereafter is payable in monthly installments of principal plus accrued interest until February 22, 2018. The Tranche 3 Loan is payable as interest-only prior to October 31, 2015 and thereafter is payable in monthly installments of principal plus accrued interest until February 22, 2018. The Tranche 4 Loan is available until December 31, 2015 and is payable in monthly installments of principal plus accrued interest until February 22, 2018. The Company has made \$145,161 and \$0 in principal payments for the three and nine months ended September 30, 2015 and 2014, respectively. The Company has made \$83,090 and \$181,520 in interest payments on the outstanding loan for the three and nine months ended September 30, 2015, respectively, and \$0 for the same periods in 2014. The agreement with Square 1 Bank sets forth various affirmative and negative covenants. The failure of the Company to comply with the covenants constitutes a default under the Loan. The covenants include the Company having at least two ongoing clinical trials at all times, the attainment of the funding conditions set forth in the agreement and covenants regarding financial reporting, limits on the Company's cash burn, incurrence of indebtedness, permitted investments, encumbrances, distributions, investments and mergers and acquisitions. The Loan is also secured by a security interest in all of the Company's personal property, excluding its intellectual property. The Company is in compliance with the covenants of the Loan as of September 30, 2015.

## 8. Stock-Based Compensation

### *Restricted Stock*

During the three and nine month period ended September 30, 2015, the Company recognized \$13,950 and \$103,950 in stock-based compensation expense related to the issuance of restricted stock to non-employees in exchange for services. There was no stock-based compensation expense recorded for restricted stock for non-employees during the three and nine month periods ended September 30, 2014.

### *Common Stock Warrants*

On March 10, 2011, the Company issued warrants to purchase 32,610 shares of common stock to third parties in consideration for a private equity placement transaction. The warrants have an exercise price of \$0.48 per share and expire 10 years from the issuance date. In connection with our initial public offering, the Company issued warrants to the underwriters for 125,000 shares of common stock issuable at \$12.50 per share upon exercise. The warrants have a five-year life and expire on July 23, 2018. These warrants do not meet the criteria required to be classified as liability awards and therefore they are treated as equity awards. As of September 30, 2015, the Company has warrants outstanding to purchase 17,392 shares of common stock issuable at \$0.48 per share and warrants to purchase 125,000 shares of common stock issuable at \$12.50 per share.

**HEAT BIOLOGICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

***Stock Options***

The following is a summary of the stock option activity for the nine months ended September 30, 2015:

|                                 | <b>Shares</b> |    | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> |
|---------------------------------|---------------|----|--|
| Outstanding, December 31, 2014  | 1,018,590     | \$ | 5.04   |
| Granted                         | 277,875       | \$ | 6.09   |
| Exercised                       | (10,272)      | \$ | 1.97   |
| Forfeited                       | (179,298)     | \$ | 6.50   |
| Outstanding, September 30, 2015 | 1,106,895     | \$ | 5.10   |

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2015 was \$3.33. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions for stock options granted during the nine months ended September 30, 2015:

|                         |        |
|-------------------------|--------|
| Dividend yield          | 0.0%   |
| Expected volatility     | 83.62% |
| Risk-free interest rate | 1.63%  |
| Expected lives (years)  | 6.0    |

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



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

The Company recognized \$245,289 and \$224,586 in stock-based compensation expense for the three months ended September 30, 2015 and 2014, respectively and \$942,136 and \$722,358 for the nine months ended September 30, 2015 and 2014, respectively for the Company's stock option awards.

The following table summarizes information about stock options outstanding at September 30, 2015:

|           | Options Outstanding |          |           | Options Vested and Exercisable |          |  |
|-----------|---------------------|----------|-----------|--------------------------------|----------|--|
|           | Weighted            |          |           | Weighted                       |          |  |
|           | Average             |          |           | Average                        |          |  |
|           | Remaining           | Weighted |           | Remaining                      | Weighted |  |
| Balance   | Contractual         | Average  | Balance   | Contractual                    | Average  |  |
| as of     | Life                | Exercise | as of     | Life                           | Exercise |  |
| 9/30/2015 | (Years)             | Price    | 9/30/2015 | (Years)                        | Price    |  |
| 1,106,895 | 7.4                 | \$5.10   | 649,421   | 6.2                            | \$3.89   |  |

As of September 30, 2015, the unrecognized stock-based compensation expense related to unvested stock options was \$3,114,452, which is expected to be recognized over a weighted average period of approximately 15.8 months.

**HEAT BIOLOGICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

**9. Financing***Public Offering*

On March 10, 2015, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Aegis Capital Corp. ("Aegis"), as representative of the several underwriters named therein (the "Underwriters"), providing for the offer and sale in a firm commitment underwritten public offering (the "Offering") of 1,640,000 shares of the Company's common stock, and 246,000 additional shares of common stock to cover over-allotments, at an offering price of \$6.50 per share. The net proceeds to the Company from the Offering and subsequent over-allotment were approximately \$11.1 million, after deducting underwriting discounts, commissions, and other third-party offering expenses. The Underwriting Agreement contains customary representations, warranties, and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended (the "Securities Act"), other obligations of the parties and termination provisions.

**10. Net Loss Per Share**

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

|  | <b>Three Months Ended</b> |                | <b>Nine Months Ended</b> |                |
|--|---------------------------|----------------|--------------------------|----------------|
|  | <b>September 30,</b>      |                | <b>September 30,</b>     |                |
|  | <b>2015</b>               | <b>2014</b>    | <b>2015</b>              | <b>2014</b>    |
| Net loss                                 | \$ (5,427,709)            | \$ (3,127,269) | \$ (14,357,325)          | \$ (8,508,592) |
| Net loss:<br>Non-controlling<br>interest | (242,244)                 | (126,865)      | (549,190)                | (330,675)      |

Edgar Filing: HEAT BIOLOGICS, INC. - Form 10-Q

|  |    |             |    |             |    |              |    |             |
|--|----|-------------|----|-------------|----|--------------|----|-------------|
| Net loss attributable to Heat Biologics, Inc.  | \$ | (5,185,465) | \$ | (3,000,404) | \$ | (13,808,135) | \$ | (8,177,917) |
| Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc. basic and diluted |    | 8,408,376   |    | 6,469,272   |    | 7,880,637    |    | 6,445,129   |
| Net loss per share attributable to Heat Biologics, Inc. basic and diluted  | \$ | (0.62)      | \$ | (0.46)      | \$ | (1.75)       | \$ | (1.27)      |

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

**For the Nine Months Ended**

**September 30,**

|                           | <b>2015</b> | <b>2014</b> |
|---------------------------|-------------|-------------|
| Outstanding stock options | 1,106,895   | 836,961     |
| Common stock warrants     | 17,392      | 17,392      |
| Underwriters warrants     | 125,000     | 125,000     |

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

**11. 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. 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.

In accordance with FASB ASC 740, *Accounting for Income Taxes*, the Company reflects in the accompanying unaudited 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, 2015 and December 31, 2014, 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 consolidated statements of operations and comprehensive loss. As of September 30, 2015 and December 31, 2014, the Company had no such accruals.



## 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 appearing elsewhere in this quarterly report. 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 condensed consolidated financial statements and the audited condensed consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission on March 27, 2015 (the 2014 Annual Report ). This discussion may contain forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements.*

### OVERVIEW

We are a cancer immunotherapy company engaged in developing novel allogeneic, off-the-shelf cellular therapeutic vaccines to combat a wide range of cancers and infectious diseases. Our proprietary *ImPACT* Immune Pan Antigen Cytotoxic Therapy has been designed to deliver live, genetically-modified, irradiated human cells which secrete a broad spectrum of disease-associated antigens together with a potent immune response stimulator called gp96. The secreted antigen-gp96 complexes educate and activate a patient's immune system to recognize and kill diseased cells. In cancer patients our *ImPACT* therapy generates anti-cancer immune responses by mobilizing and activating cytotoxic killer T cells that target multiple cancer antigens, thus harnessing a patient's own immune system to fight cancer. We recently announced the development of our next-generation *ComPACT* combination immunotherapy, which combines a pan-antigen T cell priming vaccine and T cell co-stimulator in a single product. This platform has been engineered to incorporate various fusion proteins targeting co-stimulatory receptors (OX40, ICOS, 4-1BB), enabling the combination of two important immunotherapy pathways in a single therapy.

Unlike autologous or personalized therapeutic vaccine approaches which require extraction and processing of cancer or blood from each individual patient, our *ImPACT* and *ComPACT* therapeutic vaccines are fully allogeneic and do not require extraction of an individual patient's material or custom manufacturing. Rather our vaccines are made using existing human cell lines which can be mass-produced for immediate use in all patients with the same disease. As such, we believe our off-the-shelf, immunotherapy approach offers logistical, manufacturing and cost of goods benefits compared to one-off autologous patient-specific approaches.

Currently, we have completed enrollment in the double-blinded randomized arms of our Phase 2 trial with HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC), and are conducting a Phase 2 trial of HS-110 (viagenpumatacel-L) in combination with low-dose metronomic cyclophosphamide and a Phase 1b trial of HS-110 (viagenpumatacel-L) in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC).

## **HS-410**

HS-410 (vesigenurtacel-L) is a biologic product comprising a bladder cancer cell line genetically modified using our *ImPACT* technology platform to secrete a wide range of bladder cancer antigens bound to gp96 molecules and thereby activate a T cell mediated pan-antigen immune response against the patient's bladder cancer.

We have completed enrollment in the double-blinded randomized arms of our Phase 2 trial, evaluating HS-410 either in combination with standard of care, bacillus Calmette-Guérin (BCG), or HS-410 alone, in patients with high risk, non-muscle-invasive bladder cancer (NMIBC). The Phase 2 trial will examine safety, tolerability, immune response and preliminary clinical activity of HS-410. The primary endpoint is one-year disease free survival. In October 2015, we completed enrollment of the full 75 patients in the blinded, randomized, placebo-controlled arms of the Phase 2 clinical trial. We are enrolling an additional 25 patients to evaluate HS-410 as a monotherapy in the unblinded, open-label arm, which we expect to complete by late 2015 or early 2016. We expect to report topline efficacy, immune-response and safety results in the fourth quarter of 2016.

On March 5, 2015, we were notified that the U.S. Food and Drug Administration ( FDA ) granted Fast Track designation for our HS-410 for the treatment of NMIBC. The Fast Track program is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The advantages of Fast Track designation include actions to expedite development, including opportunities for frequent interactions with the FDA review team to discuss all aspects of developments to support approval and eligibility for priority review depending on clinical data at the time of Biologics License Application ( BLA ) submission. We believe that this designation will expedite our development of HS-410.

On January 26, 2015, we announced positive data from two patients in the Phase 1 portion of our Phase 1/2 clinical trial of HS-410 in NMIBC. More specifically, analysis of tumor-infiltrating lymphocytes in one patient after surgery and induction BCG followed by six weeks of HS-410 demonstrated an approximately 70-fold increase in CD8 expression (a marker for CD8+ killer T cells) within the tumor, which was not associated with any increase in CD4 expression (a marker for CD4+ helper T cells). When the patient returned at week 21, the trend continued and an approximate 750-fold increase in CD8 was observed, without any increase in CD4 expression. We also reported that with respect to a second patient, a non-specific immune infiltrate was noted on week seven to be slightly increased as compared to baseline, but which consisted of both CD4+ and CD8+ T cells. This second patient returned with recurrent disease at week 13, when the repeat biopsy showed no further increase in the immune infiltrate.

## **HS-110**

HS-110 (Viagenpumatucel-L) is a biologic product comprising a lung cancer cell line that has been genetically modified using our *ImPACT* technology platform to secrete a wide range of lung cancer-associated antigens bound to gp96 proteins and activate a T-cell mediated pan-antigen immune response against the patient's lung cancer.

We are currently conducting a Phase 1b clinical trial evaluating HS-110 in combination with Bristol-Myers Squibb's PD-1 inhibitor nivolumab (Opdivo®) in patients with non-small cell lung cancer (NSCLC). The multicenter, open label trial is expected to initially enroll 18 patients and is designed to accommodate rapid cohort expansion up to 63 patients total. This trial is evaluating the safety and efficacy of HS-110 in combination with nivolumab in patients with NSCLC whose cancers have progressed after first-line therapy. Primary and secondary trial endpoints include safety and tolerability, immune response, overall response rate and progression-free survival. Top-line objective response rate and 6-month progression free survival (PFS) data are expected by the end of 2016 for these first 18 patients.

Our Phase 2 clinical trial evaluating HS-110 in combination with low dose cyclophosphamide versus chemotherapy alone in third-line or fourth-line NSCLC patients completed enrollment of approximately 65 patients. These patients will be followed for immune response and overall survival with data expected to be reported in the fourth quarter of



2016.

***ComPACT***

On June 15, 2015, we announced the development of a next-generation platform incorporating various T cell costimulatory ligand fusion proteins into the gp96-Ig expression vector. *ComPACT* combines a pan-antigen T cell priming vaccine and T cell co-stimulator in a single product, offering the potential benefits of combination immunotherapy in a single drug without the need for multiple independent biologic products. *ComPACT* has been engineered to incorporate various fusion proteins targeting co-stimulatory receptors (OX40, ICOS, 4-1BB), enabling the combination of two important immunotherapy pathways in a single drug. We expect to announce our selection of the first product candidate based on the *ComPACT* platform in the first quarter of 2016.

We commenced active operations in June 2008. Our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates and undertaking preclinical and clinical studies of our most advanced product candidates. To date, we have not generated any revenues and have financed our operations with net proceeds from the private placement of our preferred stock, our initial public offering in which we received gross proceeds of \$27.0 million and net proceeds of \$24.3 million, our recent public offering that was completed on March 16, 2015 of 1,886,000 shares of our common stock at a closing price of \$6.50 per share for gross proceeds of \$12.3 million and net proceeds to us of \$11.1 million, and our debt commitments. As of September 30, 2015, we had an accumulated deficit of (\$37,943,582). We had net losses of (\$5,427,709) and (\$3,127,269) for the three months ended September 30, 2015 and 2014 respectively, and net losses of (\$14,357,325) and (\$8,508,592) for the nine months ended September 30, 2015 and 2014, respectively. We expect to incur significant expenses and increasing 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 initiate and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. 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. Accordingly, there is substantial doubt that we can continue as an on-going business for the next twelve months unless we obtain additional capital. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings 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.

## **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 Company has elected to follow the extended transition period guidance provided for in Securities Act Section 7(a)(2)(B) for complying with new or revised accounting standards. The Company will disclose the date on which adoption of such standards is required for non-emerging growth companies and the date on which the Company will adopt the recently issued accounting standards.

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

.

Stock-based compensation,

.

Clinical and regulatory costs, and

.

Research and development costs

## RESULTS OF OPERATIONS

### Comparison of the Three Months ended September 30, 2015 and 2014

*Research and development expense.* Research and development expense for the three months ended September 30, 2015 was \$677,151 compared to \$1,025,442 for the three months ended September 30, 2014. The 34% decrease of \$348,291 from the three months ended September 30, 2014 to the same period of 2015 is attributable to a decrease of \$418,851 in pre-manufacturing costs associated with preparing to produce vaccines for use in our clinical trials (costs of vaccine production are now included in clinical and regulatory expense), as well as decreases in patent, license and other professional fees of \$64,036. These decreases are offset by increases of \$97,055 in compensation costs associated with an increase in pay to certain key employees as well as an increase in staff, \$23,932 in lab supplies and \$13,609 in depreciation related to the build out of the lab facility and other associated costs.

*Clinical and regulatory expense.* Clinical and regulatory expense for the three months ended September 30, 2015 was \$3,718,902 compared to \$1,258,566 for the three months ended September 30, 2014. The 195% increase of \$2,460,336 from the three months ended September 30, 2014 to the same period of 2015 is primarily attributable to increases in costs related to the production of vaccines for our clinical trials of \$1,083,953, increased investigator payments of \$672,345, and increased clinical trial execution costs of \$562,409. Additionally, personnel cost, including consultants, increased by \$217,564 primarily due to an increase in staff. These increases are offset by \$60,507 for taxes expensed during 2015 associated with clinical trial execution in Australia which are reimbursable. The remaining \$15,428 change is attributable to other operating costs.

*General and administrative expense.* General and administrative expense for the three months ended September 30, 2015 was \$947,392 compared to \$832,101 for the three months ended September 30, 2014. The 14% increase of \$115,291 from the three months ended September 30, 2014 to the same period of 2015 is primarily attributable to an increase in personnel costs including recruiting fees of \$95,805. The remaining \$19,486 change is attributable to changes in various other expenses.

*Interest income.* Interest income was \$20,121 for the three months ended September 30, 2015 compared to \$9,740 for the three months ended September 30, 2014. The increase of \$10,381 is due to the investment in various short-term financial instruments that generated interest income during the quarter.

*Other income (expense).* Other income was \$4,449 for the three months ended September 30, 2015 as compared to other expense of \$12,762 for the three months ended September 30, 2014. Other income is primarily due to the reimbursement of taxes expensed during 2014 associated with clinical trial execution in Australia. Other expense is

primarily due to the stock warrant liability revaluation during the three months ended September 30, 2014. The Company had no stock warrant liability after September 30, 2014.

*Interest expense.* Interest expense was \$108,834 for the three months ended September 30, 2015 compared to \$8,138 for the same period of 2014, all of which is attributable to the Square 1 Bank loans, the first of which, the Tranche 1 Loan, was entered into in August 2014. As of September 30, 2015 we had drawn down three of the four Tranche Loans and expect to draw the last tranche by the end of the year.

#### **Comparison of the Nine Months ended September 30, 2015 and 2014**

*Research and development expense.* Research and development expense for the nine months ended September 30, 2015 was \$1,767,942 compared to \$2,425,404 for the nine months ended September 30, 2014. The 27% decrease of \$657,462 from the nine months ended September 30, 2014 to the nine months ended September 30, 2015 is attributable to a decrease of \$954,054 in pre-manufacturing costs associated with preparing to produce vaccines for use in our clinical trials (costs of vaccine production are now included in clinical and regulatory expense), as well as decreases in patent, license and other professional fees of \$168,100. These decreases are offset by increases of \$243,850 in compensation costs associated with an increase in pay to certain key employees as well as new hires, \$166,908 in lab supplies and other costs, and \$53,934 in depreciation related to the build out of the lab facility and other associated costs.

*Clinical and regulatory expense.* Clinical and regulatory expense for the nine months ended September 30, 2015 was \$9,261,529 compared to \$3,218,137 for the nine months ended September 30, 2014. The 188% increase of \$6,043,392 from the nine months ended September 30, 2014 to the same period of 2015 is primarily attributable to increases in costs related to the production of vaccines for our clinical trials of \$1,963,624, increased investigator payments of \$1,777,528, and increased clinical trial execution costs of \$1,513,059. Additionally, personnel cost, including consultants, increased by \$451,539, professional fees increased by \$251,020, travel and other costs increased by \$86,622.

*General and administrative expense.* General and administrative expense for the nine months ended September 30, 2015 was \$3,150,394 compared to \$2,844,883 for the nine months ended September 30, 2014. The 11% increase of \$305,511 from the nine months ended September 30, 2014 to the same period of 2015 is attributable to \$229,969 related to an increase in pay to certain key employees, \$87,415 related to an increase in professional services such as accountants, attorneys and investor relations, offset by a decrease of \$11,873 in other administrative costs.

*Interest income.* Interest income was \$49,970 for the nine months ended September 30, 2015 as compared to \$27,261 for the nine months ended September 30, 2014. The increase of \$22,709 is due to the investment in various short-term financial instruments that generated interest income during the period.

*Other income (expense).* Other income was \$29,909 for the nine months ended September 30, 2015 as compared to other expense of \$39,291 for the nine months ended September 30, 2014. Other income is due to the reimbursement of taxes expensed during 2014 associated with clinical trial execution in Australia. Other expense is due to the stock warrant liability revaluation during the nine months ended September 30, 2014. The Company had no stock warrant liability after September 30, 2014.

*Interest expense.* Interest expense for the nine months ended September 30, 2015 was \$257,339, compared to \$8,138 for the nine months ended September 30, 2014, all of which is attributable to the Square 1 Bank loans, the first of which, the Tranche 1 Loan, was entered into in August 2014. As of September 30, 2015 we had drawn down three of the four Tranche Loans and expect to draw the last tranche by the end of the year.

#### **Balance Sheet at September 30, 2015 and December 31, 2014**

*Prepaid expenses and other current assets.* Prepaid expenses and other current assets were \$986,264 as of September 30, 2015 compared to \$863,227 as of December 31, 2014. The increase of \$123,037 was primarily due to an increase in the amount paid in advance to our clinical research organizations (CRO) as we progress with our Phase 2 trial for HS-410 and Phase 1b trial for HS-110.

*Accounts Payable.* Accounts payable was \$936,361 as of September 30, 2015 compared to \$1,367,426 as of December 31, 2014. The decrease of \$431,065 was primarily related to a payable that was due to one of our drug manufacturers at December 31, 2014, which was subsequently paid in the first quarter of 2015.

*Accrued Expenses and Other Payables.* Accrued expenses were \$2,074,174 as of September 30, 2015 compared to \$805,968 as of December 31, 2014. The increase of \$1,268,206 was primarily related to the increase of subjects enrolled in our clinical trials.

*Long Term Debt Including Current Portion.* Total debt was \$4,885,646 of which \$2,053,859 was current as of September 30, 2015 compared to total debt of \$2,711,589 of which \$397,465 was current as of December 31, 2014.

As of September 30, 2014 we only had outstanding debt from Tranche 1 of the Square 1 loan which was drawn down on in August 2014. Tranche 2 was drawn down in November 2014. As of September 30, 2015, we had drawn down \$1,500,000 under each of Tranche 1 and Tranche 2, and \$2,250,000 under Tranche 3 for a total of \$5,250,000 in principal amount.

*Foreign currency translation.* The foreign currency translation adjustment included in other comprehensive income was \$64,238 for the nine months ended September 30, 2015 and \$0 for the same period of 2014. The functional currency of the entities located outside the United States of America (the foreign entities) is the applicable local currency. 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.

## LIQUIDITY AND CAPITAL RESOURCES

### Sources of liquidity

To date, we have not generated any revenues. Since our inception in June 2008, we have financed our operations principally through private placements, our July 2013 initial public offering, our March 2015 public offering, and debt commitments. The total gross proceeds from the March 2015 offering and subsequent over-allotment option was \$12.3 million, before underwriting discounts, commissions and other offering expenses payable by us. The net proceeds to us were approximately \$11.1 million. We believe that our existing cash and cash equivalents will not be sufficient to meet our anticipated cash needs for the next twelve months. We intend to spend substantial amounts on research and development and clinical and regulatory activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, and the enhancement and protection of our intellectual property. We will need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. To meet our financing needs, we are considering multiple alternatives, including, but not limited to, current and additional equity financings, debt financings and/or funding from partnerships or collaborations. There can be no assurance that we will be able to complete any such transactions on acceptable terms or otherwise. If we are unable to obtain the necessary capital, we will need to pursue a plan to scale back our operations, license or sell our assets, seek to be acquired by another entity and/or cease operations. As of September 30, 2015, we had \$14,953,925 in cash and cash equivalents and short term investments.

Our cash and cash equivalents are currently held in an interest-bearing checking and money market account and short term investment grade securities.

### Cash flows

*Operating activities.* The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. The significant increase in cash used in operating activities for the nine months ended September 30, 2015 compared to the same period of 2014 is due to an increase in clinical and regulatory expenses as we began and continued clinical trials. Additionally, there was an increase in other operational costs primarily associated with increases in headcount and/or consultants in all departments.

*Investing activities.* Cash provided by investing activities for the nine months ended September 30, 2015 was primarily from proceeds from maturities and purchases of various short-term investments as well as the purchase of property and equipment. Cash provided by investing activities during the nine months ended September 30, 2014 was



from proceeds from maturities of short-term investments offset by purchase of property and equipment.

*Financing activities.* Cash provided by financing activities during the nine months ended September 30, 2015 was primarily from the March 2015 public offering and exercise of the over-allotment option which generated net proceeds of approximately \$11.1 million (after deduction of offering expenses) as well as \$2.2 million in proceeds from Tranche 3 of the Loan.

### **Funding requirements**

We believe that our existing cash and cash equivalents will not be sufficient to meet our anticipated cash needs for the next twelve months. To meet our financing needs, we are considering multiple alternatives, including, but not limited to, current and additional equity financings, debt financings and/or funding from partnerships or collaborations. Thereafter, we intend to meet our financing needs through the issuance of equity or debt and/or funding from partnerships or collaborations.

### **OFF-BALANCE SHEET ARRANGEMENTS**

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

### **ITEM 3.**

#### **QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not applicable to smaller reporting companies.

**ITEM 4.**

**CONTROLS AND PROCEDURES.**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015. 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 Securities Exchange Act of 1934, as amended ( 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. 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, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

## PART II OTHER INFORMATION

### ITEM 1.

#### LEGAL PROCEEDINGS.

None.

### ITEM 1A.

#### RISK FACTORS.

Aside from the items below there have been no changes to our risks that may materially affect our business as are reported in our Annual Report on Form 10-K for the year ended December 31, 2014, filed on March 27, 2015.

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

We currently have no products for sale and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA, and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, marketing, adverse event reporting and recordkeeping of our product candidates. Until, and unless, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot commercialize our product candidates and will not have product revenues. For the foreseeable future, we will have to fund all of our operations from equity and debt offerings, cash on hand, grants, and our Square 1 Bank debt facility. We believe that due to our current cash position and estimates of expenses, there is sufficient doubt about our ability to continue as a going concern. In addition, changes may occur that would consume our available capital at a faster pace than expected, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation. Moreover, pre-clinical studies and clinical trials may not start or be completed as we forecast and may not achieve the desired results. Therefore, we expect that we will seek additional sources of funding, such as additional financing or grant funding, and additional financing may not be available on favorable terms, if at all. Our ability to raise capital through the sale of equity may be limited by the various rules of the Securities and Exchange Commission and the Nasdaq Capital market which place limits on the number of shares of stock that may be sold. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts,

and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

***We may continue to generate operating losses and experience negative cash flows and it is uncertain whether we will achieve profitability.***

For the nine months ended September 30, 2015 and the year ended December 31, 2014, we incurred a net loss of (\$14,357,325) and (\$12,243,211), respectively. We have an accumulated deficit of (\$37,943,582) through September 30, 2015. 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 the 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 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 pre-clinical development and conduct clinical trials for product candidates;

.  
seek regulatory approvals for product candidates;

.  
implement additional internal systems and infrastructure; and

.  
hire additional personnel.

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



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

Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and initiate and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. There are no other commitments by any person for future financing. Our securities may be offered to other investors at a price lower than the price per share offered to current stockholders, or upon terms which may be deemed more favorable than those offered to current stockholders. In addition, the issuance of securities in any future financing, including under our Controlled Equity Offering<sup>SM</sup> sales agreement with Cantor Fitzgerald & Co. may dilute an investor's equity ownership and have the effect of depressing the market price for our securities. Moreover, we may issue derivative securities, including options and/or warrants, from time to time, to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and/or may have to curtail certain, if not all, of our business objectives and plans.

## **ITEM 2.**

### **UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

#### **RECENT SALES OF UNREGISTERED SECURITIES**

On August 30, 2015, we issued 10,000 shares of our common stock to an investor relations firm as partial consideration for services rendered pursuant to the terms of an agreement that we entered into with such firm.

These shares were issued upon the exemption from the registration provisions of the Securities Act of 1933 provided for by Section 4(a)(2) thereof for transactions not involving a public offering. Use of this exemption is based on the following facts:

Neither we nor any person acting on our behalf solicited any offer to buy nor sell securities by any form of general solicitation or advertising.

- At the time of the purchase, the firm was an accredited investor, as defined in Rule 501(a) of the Securities Act.
- The firm has had access to information regarding our company and is knowledgeable about us and our business affairs.
- Shares of common stock issued to the firm were issued with a restrictive legend and may only be disposed of pursuant to an effective registration or exemption from registration in compliance with federal and state securities laws.

### **USE OF PROCEEDS**

In connection with our initial public offering, we sold 2,700,000 (including the 200,000 over-allotment option shares) shares of our common stock at a price of \$10.00 per share. Aggregate gross proceeds from the IPO, were \$27.0 million and net proceeds received after underwriting commissions and offering expenses of \$2.7 million were \$24.3 million. As of September 30, 2015, we have used all net proceeds derived from the IPO in connection with our clinical trials, manufacturing and general and administrative expenses. This was in accordance with our planned use as described in the prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

### **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, which is incorporated herein by reference.

**SIGNATURES**

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

**HEAT BIOLOGICS, INC.**

|                        |     |   |
|------------------------|-----|---|
| Date: October 30, 2015 | By: | /s/ JEFFREY A. WOLF<br>Jeffrey A. Wolf<br><i>Chairman and Chief Executive Officer</i><br><i>(Principal executive officer)</i>         |
| Date: October 30, 2015 | By: | /s/ STEPHEN J. DIPALMA<br>Stephen J. DiPalma<br><i>Chief Financial Officer</i><br><i>(Principal financial and accounting officer)</i> |

**EXHIBIT INDEX**

| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| <u>31.1</u> *      | Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| <u>31.2</u> *      | Certification of Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| <u>32.1</u> *      | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| <u>32.2</u> *      | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| 101.INS*           | XBRL Instance Document  |
| 101.SCH*           | XBRL Taxonomy Extension Schema Document   |
| 101.CAL*           | XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.DEF*           | XBRL Taxonomy Extension Definition Linkbase Document  |
| 101.LAB*           | XBRL Taxonomy Extension Label Linkbase Document   |
| 101.PRE*           | XBRL Taxonomy Extension Presentation Linkbase Document  |

\*

Filed herewith.