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, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 001-35994

Heat Biologics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2844103**
(State or other jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
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	☐	Accelerated filer	☐
Non-accelerated filer (Do not check if smaller reporting company)	☐	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 November 9, 2016 there were 23,883,373 shares of Common Stock, $0.0002 par value per share, outstanding.

HEAT BIOLOGICS, INC.

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FORWARD-LOOKING STATEMENTS

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

Forward-looking statements are not guarantees of future performance and our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, our ability to raise additional capital to support our clinical development program and other operations, our ability to develop products of commercial value and to identify, discover and obtain rights to additional potential product candidates, our ability to protect and maintain our intellectual property and the ability of our licensors to obtain and maintain patent protection for the technology or products that we license from them, the outcome of research and development activities, our reliance on third-parties, competitive developments, the effect of current and future legislation and regulation and regulatory actions, as well as other risks described more fully in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission (the "SEC"). Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A. "Risk Factors" and elsewhere herein and those identified under Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on February 18, 2016. 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," the "Company," "we," "us" and "our" refer to Heat Biologics, Inc.

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	September 30, 2016 (unaudited)	December 31, 2015
Current Assets		
Cash and cash equivalents	$ 8,464,635	$ 4,939,955
Investments, held to maturity (net)	—	6,689,643
Accounts receivable	131,842	—
Prepaid expenses and other current assets	528,964	869,158
Total Current Assets	9,125,441	12,498,756
Property and Equipment, net	392,895	445,733
Other Assets		
Restricted cash	101,166	101,151
Deposits	69,798	69,798
Related party receivable	103,017	58,017
Deferred financing costs	—	21,600
Total Other Assets	273,981	250,566
Total Assets	$ 9,792,317	$ 13,195,055
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 501,225	$ 1,980,676
Accrued expenses and other liabilities	830,173	1,846,907
Current portion of long term debt	2,040,979	3,133,958
Total Current Liabilities	3,372,377	6,961,541
Long Term Liabilities		
Long term debt, net of discount and current portion	839,560	3,589,036
Other long term liabilities	439,248	149,748
Total Liabilities	4,651,185	10,700,325
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.0002 par value; 50,000,000 shares authorized, 22,202,465 and 8,424,641 shares issued and outstanding at September 30, 2016 (unaudited) and December 31, 2015, respectively	4,124	1,366
Additional paid-in capital	60,704,297	48,566,451
Accumulated deficit	(53,532,473)	(44,430,703)
Accumulated other comprehensive loss	(149,545)	(86,584)
Total Stockholders' Equity– Heat Biologics, Inc.	7,026,403	4,050,530
Non-Controlling Interest	(1,885,271)	(1,555,800)
Total Stockholders' Equity	5,141,132	2,494,730
Total Liabilities and Stockholders' Equity	$ 9,792,317	$ 13,195,055

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,	
	2016	2015	2016	2015
Revenue:				
Licensing revenue	$ 220,233	$ —	$ 220,233	$ —
Operating expenses:				
Research and development	559,177	677,151	1,514,257	1,767,942
Clinical and regulatory	1,133,956	3,718,902	5,613,209	9,261,529
General and administrative	820,574	947,392	2,935,030	3,150,394
Total operating expenses	2,513,707	5,343,445	10,062,496	14,179,865
Loss from operations	(2,293,474)	(5,343,445)	(9,842,263)	(14,179,865)
Interest income	5,445	20,121	24,400	49,970
Other income, net	734,509	4,449	757,044	29,909
Interest expense	(110,468)	(108,834)	(370,422)	(257,339)
Total non-operating income (expenses), net	629,486	(84,264)	411,022	(177,460)
Net loss	(1,663,988)	(5,427,709)	(9,431,241)	(14,357,325)
Net loss – non-controlling interest	(47,042)	(242,244)	(329,471)	(549,190)
Net loss attributable to Heat Biologics, Inc.	$ (1,616,946)	$ (5,185,465)	$ (9,101,770)	$ (13,808,135)
Net loss per share attributable to Heat Biologics, Inc.—basic and diluted	$ (0.08)	$ (0.62)	$ (0.59)	$ (1.75)
Weighted-average number of common shares used in net loss per share attributable to common stockholders—basic and diluted	19,420,026	8,408,376	15,371,267	7,880,637
Other comprehensive loss:				
Net loss	(1,663,988)	(5,427,709)	(9,431,241)	(14,357,325)
Unrealized loss on foreign currency translation	(36,387)	(27,244)	(62,961)	(64,238)
Total other comprehensive loss	(1,700,375)	(5,454,953)	(9,494,202)	(14,421,563)
Comprehensive loss attributable to non-controlling interest	(47,042)	(242,244)	(329,471)	(549,190)
Comprehensive loss	$ (1,653,333)	$ (5,212,709)	$ (9,164,731)	$ (13,872,373)

See Notes to Consolidated Financial Statements

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

	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non-Controlling Interest	Total Stockholders Equity
Balance at December 31, 2015	$ 1,366	$ 48,566,451	$ (44,430,703)	$ (86,584)	$ (1,555,800)	$ 2,494,730
Public offering, 9,100,000 shares, net of underwriters' discounts	1,820	6,285,430	—	—	—	6,287,250
Exercise of warrants, 2,773,982 shares	555	2,773,427	—	—	—	2,773,982
Issuance of common stock, 1,898,842 shares	380	3,027,297	—	—	—	3,027,677
Stock issuance costs	—	(408,810)	—	—	—	(408,810)
Stock-based compensation	3	460,502	—	—	—	460,505
Other comprehensive loss	—	—	—	(62,961)	—	(62,961)
Net loss	—	—	(9,101,770)	—	(329,471)	(9,431,241)
Balance at September 30, 2016	**$ 4,124**	**$ 60,704,297**	**$ (53,532,473)**	**$ (149,545)**	**$ (1,885,271)**	**$ 5,141,132**

See Notes to Consolidated Financial Statements

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

	Nine Months Ended September 30,	
	2016	**2015**
Cash Flows from Operating Activities		
Net loss	$ (9,431,241)	$ (14,357,325)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	98,774	84,373
Amortization of deferred financing costs and debt issuance costs	77,231	75,818
Amortization of held to maturity investment premium	32,733	102,618
Stock-based compensation	460,505	1,046,086
Increase (decrease) in cash arising from changes in assets and liabilities:		
Prepaid expenses, restricted cash and other current assets	261,700	(157,440)
Deposits	—	(50,000)
Related party receivable	(45,000)	(9,375)
Accounts payable	(1,485,735)	(385,161)
Accrued expenses and other liabilities	(1,030,413)	1,260,355
Other long term liabilities	289,500	12,228
Net Cash Used in Operating Activities	(10,771,946)	(12,377,823)
Cash Flows from Investing Activities		
Proceeds from maturities of short-term investments	6,656,910	14,943,468
Purchases of short term investments	—	(11,090,091)
Purchase of property and equipment	(45,936)	(106,838)
Net Cash Provided by Investing Activities	6,610,974	3,746,539
Cash Flows from Financing Activities		
Proceeds from public offering, net of underwriting discounts	6,287,250	11,400,870
Proceeds from issuance of common stock, net of commission	3,027,677	—
Proceeds from exercise of warrants	2,773,982	—
Stock issuance costs	(387,210)	(302,461)
Proceeds from long term debt	—	2,242,575
Payments on long term debt	(3,919,686)	(145,161)
Net Cash Provided by Financing Activities	7,782,013	13,195,823
Effect of exchange rate changes on cash and cash equivalents	(96,361)	(67,905)
Net Increase in Cash and Cash Equivalents	3,524,680	4,496,634
Cash and Cash Equivalents – Beginning of Period	4,939,955	3,714,304
Cash and Cash Equivalents – End of Period	$ 8,464,635	$ 8,210,938
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 293,189	$ 257,339

See Notes to Consolidated Financial Statements

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 and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2016.

The consolidated financial statements as of and for the three and nine months ended September 30, 2016 and 2015 included in this Quarterly Report on Form 10-Q are unaudited. The balance sheet as of December 31, 2015 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, 2015 filed with the SEC on February 18, 2016 (the "2015 Annual Report").

The accompanying consolidated financial statements as of and for the three and nine months ended September 30, 2016 and 2015 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 is the applicable local currency (the foreign entities). Assets and liabilities of the foreign entities are translated at period-end exchange rates. The 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, 2016 and December 31, 2015, the Company 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 an accumulated deficit of approximately $53.5 million as of September 30, 2016 and a net loss of approximately $9.4 million for the nine months ended September 30, 2016, 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 within one year after the audited financial statements are issued. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings (including through the "at-the-market" Issuance Sales Agreement (the "FBR Sales Agreement") that it entered into with FBR Capital Markets & Co. ("FBR") in August 2016), debt financings, partnerships, collaborations and other funding transactions. There can be no assurance that the Company will be able to meet the requirements for use of the FBR Sales Agreement or to complete any such transactions on acceptable terms or otherwise. On April 1, 2016, the Company implemented a cost-savings plan and focused corporate strategy involving reductions in headcount as well as a deferral of a portion of annual base salaries for the Company's leadership team to decrease operating costs. These cost-saving measures are intended to significantly reduce the Company's cost structure and scale the organization appropriately for its current goals. The Company has, and plans to continue to, direct its resources primarily to enable the completion of its Phase 2 clinical trial of HS-410 for the treatment of non-muscle invasive bladder cancer (NMIBC) and to advance the Phase 1b trial evaluating HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of non-small cell lung cancer (NSCLC). The Company has sufficient cash and cash equivalents to fund its clinical trials until the HS-410 Phase 2 data is released. If the Company is unable to obtain the necessary capital required to maintain operations, it will need to pursue a plan to license or sell its assets, seek to be acquired by another entity and/or cease operations.

Revenue Recognition

The Company recognizes revenues from license or research and research and development agreements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

For revenue agreements with multiple-element arrangements, the Company allocates revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable by first using vendor-specific objective evidence, if available, and then third-party evidence. If neither exists, the Company uses its best estimate of selling price for that deliverable. Revenue allocated to an element is then recognized when the four basic revenue recognition criteria are met.

Revenue associated with nonrefundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected period of performance. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. If not deemed substantive, the Company recognizes such milestones as revenue on a straight-line basis over the remaining expected performance period under the arrangement.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, and the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Revenue related to research and development grants is recognized when the related research expenses are incurred and the Company's specific performance obligations under the terms of the respective contracts are satisfied. Revenue recognized in the consolidated statement of operations is not subject to repayment.

Recently Issued Accounting Pronouncements

In August 2016, FASB issued Accounting Standards Update (ASU) No. 2016-15, *Statement of Cash Flows* (Topic 230). The guidance is intended to reduce diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The effective date for the standard for public entities is for fiscal years beginning after December 15, 2017. Early adoption is permitted, provided all amendments are adopted in the same period. The guidance requires application using a retrospective transition method. We do not anticipate ASU 2016-15 to have a material impact to our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09,*Compensation-Stock Compensation* (Topic 718): *Improvements to Employee Share-Based Payment Accounting (ASU 2016-09).* This ASU issued guidance to simplify the accounting for share-based payments. This new guidance (1) eliminates the ability to recognize excess tax benefits and certain tax deficiencies in additional paid in capital ("APIC") and requires all such items be recognized as income tax expense or benefit; (2) eliminates the presentation of excess tax benefits in the financing section of the statement of cash flows and instead requires such items be recognized in the operating activities section of the statement. This ASU is effective for fiscal years beginning after December 15, 2016, and for interim periods within those annual periods. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements or related footnote disclosures.

In February 2016, the FASB issued ASU No. 2016-02,*Leases* (Topic 842), which replaces the existing guidance in ASC 840 – *Leases*. This ASU requires a dual approach for lessee accounting under which a lessee would account for leases as finance leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of use asset and a corresponding lease liability. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset, and for operating leases, the lessee would recognize a straight-line total lease expense. This ASU is effective for fiscal years beginning after December 15, 2018, and for interim periods within those fiscal years. The Company does not expect this guidance will have a material impact on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01,*Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016-01).* ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements or related footnote disclosures.

In April 2015, the FASB issued ASU No. 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 adoption of ASU 2015-03 on January 1, 2016 resulted in the reclassification of $14,693 and $22,707 from non-current assets to an offset to long-term debt as of September 30, 2016 and December 31, 2015, respectively.

In May 2014, the FASB issued ASU No. 2014-09,*Revenue from Contracts with Customers (ASU 2014-09),* which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the new standard until fiscal years beginning after December 15, 2017 with early application permitted for fiscal years beginning after December 15, 2016. With the deferral, the new standard is effective for the Company on January 1, 2018, with early adoption permitted one year prior. The standard permits the use of either the retrospective or cumulative effect transition method. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements or related footnote disclosures.

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.

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 held its debt securities until the securities reached their maturity dates and as of September 30, 2016 the Company no longer holds debt securities. As of December 31, 2015 the Company held short term investments which consisted 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 which were carried at amortized cost using the effective interest method.

The following table summarizes information about short term investments at September 30, 2016 and December 31, 2015, respectively:

	Amortized Cost	Gross Unrealized (Losses)	Estimated Fair Value
September 30, 2016			
Certificates of deposit, tri-party repurchase agreement, corporate notes and bonds	$ —	$ —	$ —
December 31, 2015			
Certificates of deposit, tri-party repurchase agreement, corporate notes and bonds	$ 6,689,643	$ (4,948)	$ 6,684,695

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:

	September 30, 2016	December 31, 2015
Lab equipment	$ 587,367	$ 541,065
Furniture and fixtures	55,883	55,883
Computers	38,902	40,545
Total	682,152	637,493
Accumulated depreciation	(289,257)	(191,760)
Property and equipment, net	$ 392,895	$ 445,733

Depreciation expense was $98,774 and $84,373 for the nine months ended September 30, 2016 and 2015, respectively.

5. Accrued Expenses and other payables

On April 1, 2016, the Board approved a cost-savings plan and focused corporate strategy involving reductions in headcount to decrease operating costs.

Accrued expenses and other payables consist of the following:

	September 30, 2016	December 31, 2015
Accrued clinical trial expenses	$ 550,599	$ 1,192,936
Compensation and related benefits	198,974	561,082
Deferred rent	45,600	52,889
Patent fees	35,000	40,000
	$ 830,173	$ 1,846,907

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 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 $77,231 and $75,818 during the nine months ended September 30, 2016 and 2015, respectively.

7. Notes Payable

Square 1 Bank Loan

In August 2014, the Company entered into a secured loan (the “Loan”) with Square 1 Bank, which loan is held by Pacific Western Bank as successor in interest by merger to Square 1 Bank (the “Bank”). The Loan provided to the Company was a term loan in the aggregate principal amount not to exceed $7.5 million to be used to supplement working capital. The Loan was available to the Company in four tranches: $1.5 million was made available to the Company on August 22, 2014 (“Tranche 1 Loan”), $1.5 million was made available to the Company upon enrollment of the first patient in its Phase 2 clinical trial for HS-110 on December 30, 2014 (“Tranche 2 Loan”), $2.25 million 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 $2.25 million was made available to the Company upon the Bank’s receipt of evidence on December 30, 2015 of the full enrollment of our Phase 1/2 clinical trial for HS-410 (“Tranche 4 Loan”). At December 31, 2015, the Company had drawn down the entire $7.5 million available under the Loan.

The Loan accrues interest monthly at an interest rate of 3.05% plus the prime rate, or 6.30% per annum, whichever is greater. 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 was 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 was 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 payable in monthly installments of principal plus accrued interest until February 22, 2018. In September 2016, the Company paid down an additional $1.5 million in principal in consideration that the Company no longer be required to achieve the DURGA Clinical Trial Milestone. Due to the additional $1.5 million principal payment in September 30, 2016 the Tranche 1 Loan, which had a principal balance of $0.8 million, was paid in full and the remaining $0.7 million of the additional $1.5 million principal payment was applied to pay down the Tranche 2 Loan. The Company has made $2.3 million and $3.9 million in principal payments for the three and nine month periods ended September 30, 2016, respectively and $145,161 for both periods in 2015, respectively. The Company has made $84,724 and $293,189 in interest payments on the outstanding loan for the three and nine-month periods ended September 30, 2016, respectively and $83,090 and $181,520 for the same periods in 2015, respectively. The agreement with the Bank sets forth various affirmative and negative covenants. The failure of the Company to comply with one or more of the covenants constitutes a default under the Loan. The covenants were amended in February 2016 to include the following: (i) the Company on or before September 30, 2016, having enrolled at least 18 patients in the Company's DURGA (HS-110) clinical trial; (ii) the Company on or before December 31, 2016, having received favorable data readout from the Phase 2 randomized trial arms evaluating the Company's HS-410 product; and (iii) after December 31, 2016, the Bank and the Company setting additional milestone covenants based upon a Board-approved plan of the Company sufficient to fund the operations necessary to achieve such milestones. In consideration for the additional $1.5 million principal payment in September 2016, the Bank agreed that the Company will no longer be required to achieve the DURGA Clinical Trial Milestone on or before September 30, 2016. The Loan also includes 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, 2016.

8. Stock-Based Compensation

Restricted Stock

During the three and nine month periods ended September 30, 2016, the Company recognized $14,579 and $17,496 in share-based compensation expense related to issuance of shares of restricted stock to non-employees (i.e., consultants) in exchange for services. During the three and nine month periods ended September 30, 2015, the Company recognized $13,950 and $103,950 in share-based compensation expense related to issuance of shares of restricted stock to non-employees (i.e., consultants) in exchange for services.

Common Stock Warrants

In connection with the March 23, 2016 public offering, the Company issued 9,100,000 shares of common stock and warrants to purchase 6,825,000 shares of common stock. Each share of common stock was sold together with a warrant to purchase 0.75 of a share of common stock. The warrants have an exercise price of $1.00 per share and expire five years from the issuance date. The fair value of the common stock warrants as of the issuance date was approximately $2,522,754. As of September 30, 2016, warrants for 2,773,982 shares of common stock issuable at $1.00 per share have been exercised. In connection with our July 23, 2013 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 expire five years from the issuance date. On March 10, 2011, the Company issued warrants to purchase shares of common stock to third parties in consideration for a private equity placement transaction. The warrants have an exercise price of $0.48 per share and expire 10 years from the issuance date. As of September 30, 2016, the Company has issued and outstanding warrants to purchase 4,051,018 shares of common stock issuable at $1.00 per share; warrants 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. Subsequent to September 30, 2016, warrants for 375,000 shares of common stock issuable at $1.00 per share have been exercised. These warrants do not meet the criteria required to be classified as liability awards and therefore are treated as equity awards.

Stock Options

The following is a summary of the stock option activity for the nine months ended September 30, 2016:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2015	1,214,686	$ 4.93
Granted	451,339	$ 2.18
Forfeited	(446,178)	$ 1.67
Outstanding, September 30, 2016	1,219,847	$ 4.09

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2016 was $1.41. The fair value of each stock option was 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, 2016:

Dividend yield	0.0%
Expected volatility	73.90%
Risk-free interest rate	1.84%
Expected lives (years)	6.0

The risk-free interest rate is based on U.S. Treasury interest rates at the time of the grant with a term which 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 has limited 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 Company recognized $96,020 and $245,289 in share-based option compensation expense for the three months ended September 30, 2016 and 2015, respectively and $434,859 and $942,136 in share-based option compensation expense for the nine months ended September 30, 2016 and 2015, respectively for the Company's stock option awards. In addition to share-based option compensation, the Company also recognized $8,150 in common stock compensation expense for one of its employees for the three and nine months ended September 30, 2016.

The following table summarizes information about stock options outstanding at September 30, 2016:

Options Outstanding			Options Vested and Exercisable		
Balance as of 9/30/2016	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Balance as of 9/30/2016	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
1,219,847	7.2	$4.09	823,127	6.2	$4.60

As of September 30, 2016, the unrecognized stock-based compensation expense related to unvested stock options was $1,210,028, which is expected to be recognized over a weighted average period of approximately 16.6 months.

Total stock-based compensation expense, including restricted stock, stock options, and common stock was $118,749 and $259,239 for the three months ended September 30, 2016 and 2015, respectively and $460,505 and $1,046,086 for the nine months ended September 30, 2016 and 2015, respectively.

9. Financing

On August 15, 2016, Heat Biologics, Inc. (the "Company") and FBR Capital Markets & Co. ("FBR") entered into an At Market Issuance Sales Agreement (the "Sales Agreement") pursuant to which the Company may sell from time to time, at its option, shares of its common stock, par value $0.0002 per share, having an aggregate offering price of up to $10.5 million through FBR, as sales agent. The Company may sell shares of its common stock through FBR by any method permitted that is deemed an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on or through the NASDAQ Capital Market, the existing trading market for the Company's common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. Sales of shares of common stock will be made pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-199274) filed with the U.S. Securities and Exchange Commission ("SEC"), the base prospectus, dated October 23, 2014, filed as part of such registration statement and the prospectus supplement, dated August 15, 2016. FBR will be entitled to compensation at a fixed commission rate up to 3.0% of the gross proceeds per share sold through it as sales agent under the sales agreement. Beginning in August 2016 and through September 30, 2016, the Company sold 1.9 million shares of common stock under the FBR Sales Agreement resulting in net proceeds of approximately $2.8 million, after FBR's commission of $0.08 million and other expenses of $0.12 million. As of October 31, 2016, the Company has sold an addition 1.0 million shares of common stock under the Sales Agreement resulting in net proceeds of approximately $1.4 million.

Public Offering

On March 23, 2016, the Company closed the issuance and sale of 9,100,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 6,825,000 shares of its common stock, at a combined public offering price of $0.75 per share and related warrant (the "Offering"). The warrants are exercisable immediately upon issuance, expire five years after the date of issuance and have an exercise price of $1.00 per share. The net proceeds to the Company from the Offering excluding exercise of warrants, were approximately $6.1 million after deducting underwriting discounts, commissions, and other third party offering expenses. As of September 30, 2016, the Company has raised approximately $2.8 million from the exercise of 2,773,982 warrants. In connection with the Offering, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Roth Capital Partners, LLC and Aegis Capital Corp., as representatives (the "Representatives") of the several underwriters (collectively, the "Underwriters"). 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. Subsequent to September 30, 2016, warrants for 375,000 shares of common stock issuable at $1.00 per share have been exercised.

10. Net Loss Per Share

Basic and diluted net loss per common share is calculated by dividing net loss attributable 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.:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (1,663,988)	$ (5,427,709)	$ (9,431,241)	$ (14,357,325)
Net loss: Non-controlling interest	(47,042)	(242,244)	(329,471)	(549,190)
Net loss attributable to Heat Biologics, Inc.	$ (1,616,946)	$ (5,185,465)	$ (9,101,770)	$ (13,808,135)
Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc. —basic and diluted	19,420,026	8,408,376	15,371,267	7,880,637
Net loss per share attributable to Heat Biologics, Inc.—basic and diluted	$ (0.08)	$ (0.62)	$ (0.59)	$ (1.75)

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,	
	2016	2015
Outstanding stock options	1,219,847	1,106,895
Common stock warrants	4,068,410	17,392
Underwriters warrants	125,000	125,000

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 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, 2016 and December 31, 2015, 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, 2016 and December 31, 2015, the Company had no such accruals.

12. Subsequent Events

On October 25, 2016, the Company announced that it entered into an agreement with the University of Miami for the license and development of a portfolio of patents leveraging its gp96 platform to target the Zika virus and other infectious diseases. The Company formed a wholly-owned subsidiary, Zolovax, Inc. to focus on the development of gp96-based vaccines initially targeting Zika with the ability to target HIV, West Nile dengue and yellow fever, among others.

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 unaudited consolidated 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, 2015 filed with the Securities and Exchange Commission on February 18, 2016 (the "2015 Annual Report"). This discussion may contain forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements." Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth below, under Part II, Item 1A. "Risk Factors" and elsewhere herein, and those identified under Part I, Item 1A of the 2015 Annual Report.

OVERVIEW

We are an immuno-oncology company developing novel therapies intended to activate a patient's immune system to fight cancer. Using our T cell-stimulating platform technologies, *ImPACT*® (Immune Pan-Antigen Cytotoxic Therapy) and *ComPACT*™ (Combination Pan-Antigen Cytotoxic Therapy), we have generated several product candidates that we believe may be effective in treating certain forms of cancer. Our platform technologies address two synergistic mechanisms of action: activation of CD8+ T cells, or "killer" T cells; and T cell co-stimulation . We believe the use of these technologies has the potential to enhance patients' natural immune response against certain cancers.

Using our *ImPACT*® platform technology , we have developed product candidates that consist of live, genetically-modified, irradiated human cancer cells which secrete a broad spectrum of tumor-associated antigens ("TAAs") together with a potent immune response stimulator called "gp96." The secreted antigen-gp96/TAA complexes activate a patient's immune system to recognize and kill cancer cells that express the TAAs included in the product candidates, which we have engineered to address the most prevalent TAAs present in the "tumor signature" of a specific cancer.

Our *ComPACT*™ platform technology enables us to combine a pan-antigen T cell-activating vaccine and a T cell co-stimulator in a single product, offering the potential benefits of combination immunotherapy without the need for multiple independent biologic products. Using *ComPACT*™, we have engineered new product candidates that incorporate various ligand fusion proteins targeting co-stimulatory receptors (OX40, ICOS, 4-1BB) into the gp96-Ig expression vector, resulting in a single product candidate that includes both a pan-antigen T cell-priming vaccine and a T cell co-stimulator .

Using our platform technologies, we produce product candidates from allogeneic cell lines selected to express the broadest array of commonly shared tumor antigens for a specified type of cancer. Unlike autologous or "personalized" therapeutic vaccine approaches that require the extraction of blood or tumor tissue from each patient and the creation of an individualized treatment, our product candidates are fully allogeneic, do not require extraction of an individual patient's material or custom manufacturing. As a result, our product candidates can be mass-produced and readily available for immediate patient use. Because each patient receives the same treatment, we believe that our immunotherapy approach offers logistical, manufacturing and other cost benefits compared to one-off, patient-specific approaches.

Our lead product candidates are HS-410 and HS-110. Using our *ImPACT*® platform technology, we have developed HS-410 (vesigenurtacel-L) as a product candidate to treat non-muscle invasive bladder cancer ("NMIBC") and HS-110 (viagenpumatucel-L) , intended for use in combination with an anti-PD-1 checkpoint inhibitor, as a potential treatment for patients with non-small cell lung cancer ("NSCLC"). To date, we have administered in excess of 1,000 doses of HS-410 and HS-110 collectively in over 200 patients.

Currently, we have completed enrollment in all arms of our Phase 2 trial with HS-410 in patients with NMIBC, which is our primary focus, and are conducting a Phase 1b trial of HS-110 in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb PD-1 checkpoint inhibitor, to treat patients with NSCLC. We are devoting substantially all of our resources to developing HS-410 and the advancing of the current eight patients as well as enrolling new patients in our Phase 1b clinical trial evaluating HS-110 in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb PD-1 checkpoint inhibitor, to treat patients with NSCLC. We currently do not have any products approved for sale and we have not generated any revenue from product sales since our inception. We expect to continue to incur significant expenses and to incur increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

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

Our patent portfolio is comprised of eighteen issued patents and eighteen pending patent applications. These patents and applications cover the United States, Europe, and Japan as well as several other countries having commercially significant markets.

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 significant 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 March 16, 2015 public offering in which we received gross proceeds of $12.3 million and net proceeds to us of $11.1 million, our public offering that was completed on March 23, 2016 of 9,100,000 shares of our common stock and warrants to purchase up to an aggregate of 6,825,000 shares of its common stock at a combined price of $0.75 per share for gross proceeds of $6.8 million and net proceeds to us of $6.1 million and, as of September 30, 2016, an additional $2.8 million from the exercise of 2,773,982 warrants, $2.8 million of net proceeds from sales through the At Market Issuance Sales Agreement (the "FBR Sales Agreement") with FBR Capital Markets & Co. through September 30, 2016, and our debt commitments. As of September 30, 2016, we had an accumulated deficit of approximately $53.5 million. We had net losses of approximately $1.7 million and $5.4 million for the three months ended September 30, 2016 and 2015, respectively, and net losses of approximately $9.4 million and $14.4 million for the nine months ended September 30, 2016 and 2015, 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. 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 our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our lead product candidate and, in April 2016, we implemented a cost-savings plan and focused corporate strategy involving reductions in headcount as well as a deferral of a portion of annual base salaries for our leadership team to decrease operating costs. We may take additional action to reduce our immediate cash expenditures, including re-visiting our headcount, offering vendors equity in lieu of the cash due to them and otherwise limiting our other research expenses, in order to focus our resources on our lead product candidate. We will need to generate significant revenues to achieve profitability, and we may never do so.

HS-410 – Bladder Cancer

HS-410 (vesigenurtacel-L) is a biologic product candidate comprising a cancer cell line genetically modified using our*ImPACT*® technology platform to secrete a wide range of cancer antigens related to bladder cancer bound to gp96 molecules . We believe that HS-410 has the potential to activate a T cell-mediated pan-antigen immune response that could be an effective treatment for patients with NMIBC.

Our primary focus is our Phase 2 trial evaluating HS-410 either alone or in combination with intravesical standard of care, Bacillus Calmette-Guérin (BCG), for the treatment of high-risk NMIBC. The primary endpoint is one-year disease free survival. We completed enrollment for the Phase 2 trial's three randomized, combination arms and anticipate reporting topline efficacy, immune-response and safety data in the fourth quarter of 2016.

On February 25, 2016, we announced that we will no longer enroll new patients in our Phase 2 monotherapy trial arm evaluating HS-410 alone for the treatment of NMIBC. We added the monotherapy trial arm in response to the intermittent global shortage of standard of care BCG in early 2015. The shortage has since been resolved and as such, we will no longer enroll new patients in this trial arm based on discussions with the U.S. FDA. The decision does not relate to concerns regarding the safety profile of HS-410. The 16 patients currently enrolled, out of the anticipated 25 patients, can continue receiving HS-410 monotherapy per the study protocol. We anticipate reporting topline 6-month data from these 16 patients in the fourth quarter of 2016, contemporaneous with reporting data from our three randomized Phase 2 trial arms evaluating HS-410 in combination with BCG.

On February 10, 2016, we announced that the U.S. FDA had lifted the partial clinical hold on our HS-410 Phase 2 clinical trial and that patient enrollment had resumed; clinical timelines were materially unchanged. On February 3, 2016, we announced that we had concluded that the cell line on which HS-410 is based, which is a prostate cancer cell line, had been previously misidentified as a bladder cancer cell line, that we had advised the U.S. FDA of this conclusion and that the U.S. FDA had placed our HS-410 Phase 2 clinical trial on partial clinical hold while they reviewed certain updated documentation provided by us related to the misidentification. The misidentification related to the origin of the cell line and not to the antigen profile or other characteristics of the cell line, which have been accurately characterized throughout the clinical development of HS-410. The partial clinical hold did not relate to concerns regarding the safety and efficacy of HS-410. All data generated and reported remained unchanged, including HS-410's positive safety profile, immune response and shared antigenic profile with patient tumors. Upon becoming aware of the misidentification, we amended all of the documentation necessary to correct the error, including the related investigator brochure, study protocol and informed consent form. Due to the short duration of the clinical hold, we do not expect any material change in our clinical timelines. In addition, we do not expect that the misidentification will have any adverse effect on the future clinical development of HS-410. While our rights to the prostate cancer cell line are non-exclusive, we believe that our intellectual property portfolio, which we expect to be unaffected by the misidentification, will provide us with appropriate protection for the development and potential commercialization of HS-410.

In January 2016, we reported three-month interim data from the unblinded, monotherapy cohort of our company's ongoing Phase 2 trial of HS-410 for the treatment of NMIBC at the Phacilitate Immunotherapy World Conference. In the monotherapy arm, a series of weekly intradermal injections of HS-410 is being dosed as an alternative to BCG. Images of the bladder taken from several treated patients showed changes that resemble lymphoid (T cell rich) structures that we have observed in biopsy samples, which we believe indicates that HS-410 is generating an immune response as expected. Six out of seven patients in the monotherapy arm, who had reached the 3-month timepoint after treatment with HS-410 alone, remained recurrence free. One of those patients had *carcinoma in situ* (*CIS*) – the patient population believed to be least responsive to BCG – and that patient experienced complete response.

HS-110 – Non-Small Cell Lung Cancer ("NSCLC")

HS-110 (viagenpumatucel-L) is a biologic product candidate comprising a cancer cell line that has been genetically modified using our*ImPACT*® technology platform to secrete a wide range of cancer-associated antigens related to lung cancer bound to gp96 proteins . We believe that HS-110 has the potential to activate a T cell-mediated pan-antigen immune response that could be an effective treatment for patients with NSCLC.

We are conducting a Phase 1b clinical trial evaluating HS-110 in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb PD-1 checkpoint inhibitor, to treat patients with NSCLC. The multicenter, open label trial is expected to initially enroll 18 patients and is designed to accommodate cohort expansion up to 30 patients in total. We have continued to advance the current eight patients enrolled in the Phase 1b clinical trial and in September 2016 we announced we had resumed trial enrollment through funding from the exercise of warrants. The purpose of the trial is to evaluate the safety and efficacy of HS-110 in combination with nivolumab, an FDA approved anti-PD-1 checkpoint inhibitor, 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 eight patients.

In June 2016, we reported interim study findings suggesting that the addition of HS-110 to nivolumab does not significantly alter the nivolumab safety profile to-date. In addition, case studies of three trial patients (one non-responder and two responders) have been characterized. While all three patients showed a decrease in immune cell PD-1 expression, which is consistent with nivolumab's mechanism of action, both responders also showed a decrease in immunosuppressor cells, as well as increases in activated effector T cells in the peripheral blood. Furthermore, the two responders showed an increase in CD8+ T cells in biopsy samples after treatment with the HS-110/nivolumab combination. ELISPOT analysis of patient blood samples demonstrated induction of antigen-specific immune responses to both total vaccine antigen and individual shared tumor antigens in both responding patients, but not the clinical non-responder. Finally, these responding patients also had low-grade injection site reactions in addition to rash, which the non-responder did not, suggesting their clinical and immune responses may be attributed to the HS-110 vaccine.

We also are conducting a Phase 2 clinical trial evaluating HS-110 in combination with low dose cyclophosphamide versus chemotherapy alone as a potential third-line or fourth-line treatment in patients with NSCLC. We completed enrollment of 66 patients in this study in September 2015. These patients will be followed for overall survival with data expected to be reported in the fourth quarter of 2016.

Additional Indications

We continue to evaluate other potential indications for our *ImPACT*® and *ComPACT*™ platform technologies. Specifically, using *ComPACT*™, we have developed cell lines for several other cancers with the first product candidate being a second-generation therapy for non-small cell lung cancer (HS-120). Our decision to further pursue these product candidates or any additional product candidates other than our two lead product candidates will be based in part upon available funding and partnering opportunities. On February 18, 2015, we announced a collaboration with OncoSec Medical Inc. to evaluate the feasibility of OncoSec's ImmunoPulse *in vivo* electroporation technology for intra-tumoral delivery of gp96-Ig encoding DNA plasmids to activate specific immune responses against 'private,' mutation-derived tumor neo-antigens. In April 2016, we announced the first preclinical data from this collaboration. Preclinical data demonstrated that combining Heat's *ComPACT* vaccine with OncoSec's intratumoral DNA electroporation delivery platform stimulated an expansion of neoantigen-specific CD8+ T cells, leading to a regression in both treated and untreated cancer tumors in two mouse studies (melanoma and colorectal cancer). These findings provide initial proof-of-principal and warrant further investigation.

***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 have reported preclinical data demonstrating that *ComPACT* secreting OX40L generated the most potent immune response among other *ComPACT* co-stimulator variations including TL1A, 4-1BBL and ICOSL, as well as compared to systemic delivery of OX40 agonist antibody and vaccine alone.

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 that 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.

We have 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. We will disclose the date on which adoption of such standards is required for non-emerging growth companies and the date on which we 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, 2016 and 2015

Revenue. We recognized $220,233 in research funding revenue for the quarter ended September 30, 2016 pursuant to our exclusive license agreement with Shattuck Labs, Inc. ("Shattuck") to allow Shattuck to take over the research and development of certain preclinical assets. There was no revenue for the quarter ended September 30, 2015.

Research and development expense. Research and development expense decreased by 17% to $559,177 for the quarter ended September 30, 2016 compared to $677,151 for the quarter ended September 30, 2015. The $117,974 decrease is attributable to a $59,431 reduction in consultant fees, a $52,585 decrease in compensation costs attributable to deferral of salary as part of our cost-savings plan, a $17,528 decrease in patent expense, and a $3,726 decrease in travel and related fees. These decreases are offset by a $15,296 increase in supplies as we bring more research and development capabilities in-house.

Clinical and regulatory expense. Clinical and regulatory expense decreased 70% to $1,133,956 for the quarter ended September 30, 2016 compared to $3,718,902 for the quarter ended September 30, 2015. The $2,584,946 decrease is primarily attributable to a $1,432,855 decrease in clinical trial execution costs, and a $1,005,417 decrease in production of clinical trial material, as we have focused our resources primarily to enable the completion of our Phase 2 clinical trial of HS-410 for the treatment of NMIBC and to advance the current eight patients enrolled in our Phase 1b trial evaluation of HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of NSCLC. The remaining decrease of $146,674 is attributable primarily to a $139,838 decrease in consultant costs and a $6,836 decrease in various other expenses.

General and administrative expense. General and administrative expense decreased 13% to $820,574 for the quarter ended September 30, 2016 compared to $947,392 for the quarter ended September 30, 2015. The $126,818 decrease is attributable to a $173,852 decrease in compensation costs attributable to deferral of salary and work force reductions as part of our cost-savings plan, offset by a $37,332 increase in travel-related fees. The remaining $9,702 increase is attributable to changes in various other expenses.

Interest income. Interest income was $5,445 for the quarter ended September 30, 2016 compared to $20,121 for the quarter ended September 30, 2015. The decrease of $14,676 is due to the Company's decreased investment balance during the quarter ended September 30, 2016.

Other income (expense). Other income increased to $734,509 for the quarter ended September 30, 2016 from income of $4,449 for the quarter ended September 30, 2015. Other income is primarily related to the R&D Tax Incentive for expenses associated with clinical trial activities conducted in Australia and foreign exchange rates related to the Australian dollar. The increase is primarily related to the reimbursement of the annual 2015 R&D tax credit received during the quarter ended September 30, 2016.

Interest expense. Interest expense was $110,468 for the quarter ended September 30, 2016 compared to $108,834 for the quarter ended September 30, 2015. The increase of $1,634 is de minimis.

Comparison of the Nine Months ended September 30, 2016 and 2015

Revenue. We recognized $220,233 in research funding revenue for the nine month period ended September 30, 2016 pursuant to our exclusive license agreement with Shattuck. There was no revenue for the nine month period ended September 30, 2015.

Research and development expense. Research and development expense decreased by 14% to $1,514,257 for the nine month period ended September 30, 2016 compared to $1,767,942 for the nine month period ended September 30, 2015. The $253,685 decrease was attributable to reductions in patent, license and other professional fees of $162,414 primarily associated with our decision to no longer pursue a certain technology, $84,031 decrease in consultant expense, and a $63,121 decrease in compensation costs attributable to deferral of salary as part of our cost-savings plan. These decreases are offset by an increase of $55,881 in supplies and facilities costs as we bring more research and development capabilities in-house.

Clinical and regulatory expense. Clinical and regulatory expense decreased 39% to $5,613,209 for the nine month period ended September 30, 2016 compared to $9,261,529 for the nine month period ended September 30, 2015. The $3,648,320 decrease is primarily attributable to a $3,019,292 decrease in clinical trial execution costs, and a $783,741 decrease in production of clinical trial material as we have focused our resources primarily to enable the completion of our Phase 2 clinical trial of HS-410 for the treatment of NMIBC and to advance the current eight patients enrolled in our Phase 1b trial evaluation of HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of NSCLC, a $231,638 decrease in professional services related to marketing expense for patient enrollment, and a $56,938 decrease in travel and other costs. These decreases are offset by an increase of $443,289 in personnel-related costs during the first three months of 2016 to support our clinical trials and manufacturing efforts.

General and administrative expense. General and administrative expense decreased 7% to $2,935,030 for the nine month period ended September 30, 2016 compared to $3,150,394 for the nine month period ended September 30, 2015. The $215,364 decrease is primarily related to a $245,730 decrease in compensation costs attributable to deferral of salary and work force reductions as part of our cost-savings plan, offset by a $30,366 increase in various other expenses.

Interest income. Interest income was $24,440 for the nine month period ended September 30, 2016 compared to $49,970 for the nine month period ended September 30, 2015. The decrease of $25,570 is due to the Company's decreased investment balance during 2016.

Other income (expense). Other income increased to $757,044 for the nine month period ended September 30, 2016 from $29,909 for the nine month period ended September 30, 2015. Other income is primarily related to the R&D Tax Incentive for expenses associated with clinical trial activities conducted in Australia and foreign exchange rates related to the Australian dollar. The increase is primarily related to the reimbursement of the annual 2015 R&D tax credit received during the nine months ended September 30, 2016.

Interest expense. Interest expense increased by 44% to $370,422 for the nine month period ended September 30, 2016 compared to $257,339 for the nine month period ended September 30, 2015. During the first nine months of 2015 we had drawn down three of four Tranche Loans for $5.3 million and at the end of 2015 we had drawn down all four Tranche Loans for a total of $7.5 million.

Workforce reduction. In April 2016, we implemented a cost-savings plan involving a reduction of approximately 22% of the Company's headcount to decrease operating costs. The workforce reduction is related to our plan to improve operational efficiencies and leverage cost-cutting measures. All charges related to the workforce reduction were paid as of September 30, 2016.

Comparison of the Balance Sheet at September 30, 2016 and December 31, 2015

Investments, held to maturity (net). Investments held to maturity (net) decreased to $0 as of September 30, 2016 compared to $6,689,643 as of December 31, 2015. The Company no longer holds debt securities as investments.

Accounts receivables. Accounts receivable of $131,842 represent amounts due under our exclusive license agreement with Shattuck. The company had no significant accounts receivable during 2016.

Prepaid expenses and other current assets. Prepaid expenses and other current assets were $528,964 as of September 30, 2016 compared to $869,158 as of December 31, 2015. The decrease of $340,194 was primarily due to the reduction in the amount paid in advances to our clinical research organizations (CRO) as we progress our clinical trial studies for HS-410 and HS-110.

Accounts Payable. Accounts payable was $501,225 as of September 30, 2016 compared to $1,980,676 as of December 31, 2015. The decrease of $1,479,451 was primarily related to payments to one of our drug manufacturers and two of our clinical trial investigator sites in 2016.

Accrued Expenses and Other Liabilities. Accrued expenses were $830,173 as of September 30, 2016 compared to $1,846,907 as of December 31, 2015. The decrease of $1,016,734 was primarily related to a decrease in our investigator sites during 2016 as we closed patient enrollment and our 2015 employee bonuses which were accrued at December 31, 2015 and subsequently paid in January 2016.

Long Term Debt, net of discount deferred/financing. Long term debt was $839,560 as of September 30, 2016 compared to $3,589,036 as of December 31, 2015. The decrease of $2,749,476 is due to the $1.5 million pay down in September 2016 in consideration of the DURGA Clinical Milestone and $1,613,125 in principal payments offset by the debt discount and deferred financing costs that are amortized to expense.

Other Long Term Liabilities. Other long term liabilities were $439,248 as of September 30, 2016 compared to $149,748 as of December 31, 2015. The increase is primarily related to an increase in clinical sites, each of which has a 5% to 10% holdback requirement. This holdback will be billed at the end of the respective trial. Additionally, the initial $50,000 deposit under our exclusive license agreement with Shattuck has been recorded as other long term liability and will be recognized as revenue over the term of the agreement.

Foreign currency translation. The foreign currency translation adjustment included in accumulated other comprehensive loss was $62,961 for the nine month period ended September 30, 2016 compared to $37,051 for the nine month period ended September 30, 2015.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

To date, we have not generated any significant 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, our March 2016 public offering, our August 2016 ATM sales agreement, and debt commitments. From our March 2016 public offering we have received net proceeds of approximately $6.1 million and an additional $2.8 million from the exercise of 2,773,982 warrants as of September 30, 2016. We have received net proceeds of approximately $2.8 million, after FBR's commission of $0.08 million and other expenses of $0.12 million from sales of our common stock through the FBR Sales Agreement. Although we believe our existing cash and cash equivalents will be sufficient to fund our clinical trials until the HS-410 Phase 2 data is released, 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, including sales of common stock through the FBR Sales Agreement, debt financings and/or funding from partnerships or collaborations. There can be no assurance that we will be able tomeet the requirements for use of the FBR Sales Agreement or tocomplete any such transactions on acceptable terms or otherwise. If we are unable to obtain the necessary capital, we will scale back our operations, license or sell our assets, seek to be acquired by another entity and/or cease operations. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our lead product candidate and, in April 2016, we implemented a cost-savings plan and focused corporate strategy involving reductions in headcount as well as a deferral in a portion of annual base salaries for our leadership team to decrease operating costs. We may take additional action to reduce our immediate cash expenditures, including re-visiting our headcount, offering vendors equity in lieu of the cash due to them and otherwise limiting our other research expenses, in order to focus our resources on our lead product candidate. As of September 30, 2016, we had $8.5 million in cash and cash equivalents.

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

Cash flows

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. The decrease in cash used in operating activities for the nine month period ended September 30, 2016 compared to the nine month period ended September 30, 2015 is due to the decrease in clinical and regulatory expenses as we focus our resources primarily to enable the completion of our Phase 2 clinical trial of HS-410 for the treatment of NMIBC and to advance the current eight patients enrolled in our Phase 1b trial evaluation of HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of NSCL. Additionally, there was a decrease in other operational costs primarily associated with our cost-saving plan in April 2016.

Investing activities. Cash provided by investing activities for the nine month periods ended September 30, 2016 and 2015 was primarily from proceeds from maturities of various short-term investments offset by the purchase of property and equipment.

Financing activities. Cash provided by financing activities during the nine month period ended September 30, 2016 was primarily from the March 2016 public offering which generated proceeds, net of underwriting discount of approximately $6.3 million and an additional $2.8 million from the exercise of 2,773,982 warrants. The FBR Sales Agreement which began August 2016 has generated proceeds through September 30, 2016 of approximately $3.0 million, net of commission. Stock issuance cost for the nine month period ending September 30, 2016 was $0.4 million. Cash payments on long term debt of approximately $3.9 million during the nine period ended September 30, 2016 was primarily from the $1.5 million paydown and principal payments to the Square 1 Loan. Cash provided by financing activities during the nine month period ended September 30, 2015 was primarily from the March 2015 public offering and exercise of the over-allotment option which generated proceeds, net of underwriting discount and stock issuance cost of approximately $11.1 million, as well as $2.2 million in proceeds from Tranche 3 of the Loan.

Funding requirements

Although we believe our existing cash and cash equivalents will be sufficient to fund our clinical trials until the HS-410 Phase 2 data is released, 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. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our lead product candidate and, in April 2016, we implemented a cost-savings plan and focused corporate strategy involving reductions in headcount as well as a deferral of a portion of annual base salaries for our leadership team to decrease operating costs. We may take additional action to reduce our immediate cash expenditures, including re-visiting our headcount, offering vendors equity in lieu of the cash due to them and otherwise limiting our other research expenses, in order to focus our resources on our lead product candidate. 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 Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We have adopted and maintain disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. The Company's disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016 our Principal Executive Officer and Principal 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

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) occurred during the quarter ended September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

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

ITEM 1A. RISK FACTORS.

The following information and updates should be read in conjunction with the information disclosed in Part 1, Item 1A, "Risk Factors," contained in our 2015 Annual Report. Except as disclosed below, there have been no material changes from the risk factors and uncertainties disclosed in our 2015 Annual Report.

We will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate our development programs or commercialization efforts.

During the nine months ended September 30, 2016, our operating activities used net cash of approximately $10.8 million and as of September 30, 2016 our cash and cash equivalents were approximately $8.5 million. During the year ended December 31, 2015, our operating activities used net cash of approximately $17.4 million and as of December 31, 2015 our cash and cash equivalents and short term investments were approximately $11.6 million. We have experienced significant losses since inception and have a significant accumulated deficit. As of September 30, 2016, our accumulated deficit totaled approximately $53.5 million and as of December 31, 2015, our accumulated deficit totaled approximately $44.4 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. We do not expect to derive revenue from any significant source in the near future until we or our potential partners successfully commercialize our products. Despite cost-saving measures that we implemented, we expect our expenses to increase if and when we initiate and conduct Phase 3 and other clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees and grants.

We expect that our current cash and cash equivalents together with the offering proceeds will allow us to complete the Phase 2 clinical trial for HS-410 and continue to treat the current eight patients enrolled in the Phase 1b clinical trial for HS-110. The continued enrollment of additional patients in our Phase 1b trial evaluating HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, will be dependent upon us raising additional funding. Our primary focus is to complete the Phase 2 trial of HS-410 for the treatment of NMIBC, making our business and operating results largely dependent on our efforts to complete this Phase 2 trial. As such, if the Phase 2 trial of HS-410 for the treatment of NMIBC is not successful, it would have an immediate material adverse effect on our business, operating results and financial condition.

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, 2016 and September 30, 2015, we incurred a net loss of $9.4 million and $14.4 million, respectively. For the years ended December 31, 2015 and December 31, 2014, we incurred a net loss of $21.1 million and $12.2 million, respectively. We have an accumulated deficit of $53.5 million as of September 30, 2016. We expect to continue to incur operating losses until such time, if ever, as we are able to achieve sufficient levels of revenue from operations. Our ability to achieve profitability will depend on us obtaining regulatory approval for our product candidates and market acceptance of our product offerings and our capacity to develop, introduce and sell our products to our targeted markets. There can be no assurance that any of our product candidates will be approved for commercial sale, or even if our product candidates are approved for commercial sale, that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

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

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

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.

The possible issuance of common stock subject to options and warrants may dilute the interest of stockholders.

In 2009, we adopted a 2009 Stock Option and Restricted Stock Plan (the "2009 Plan"). In 2014, we adopted a 2014 Stock Incentive Plan (the "2014 Plan") and in 2015 and 2016 we increased the number of shares of common stock that we have authority to grant under the 2014 Plan. As of September 30, 2016, awards for 2,275,012 shares of common stock have been granted under the 2009 Plan and the 2014 Plan and there were 2,343,136 shares of common stock remaining available for grant under these plans. In addition, as of September 30, 2016, we have 17,392 shares issuable upon exercise of warrants granted to third parties in connection with prior private placements of our equity securities and debt 4,051,018 shares of common stock issuable upon exercise of warrants granted to third parties in connection with our recent public offering and 125,000 shares of common stock issuable at $12.50 per share upon exercise of warrants issued to the underwriters in connection with our initial public offering. To the extent that outstanding stock options and warrants are exercised, or additional securities are issued including shares of common stock that are issued through the FBR Sales Agreement, dilution to the interests of our stockholders may occur. Moreover, the terms upon which we will be able to obtain additional equity capital may be adversely affected since the holders of the outstanding options can be expected to exercise them at a time when we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than those provided in such outstanding options.

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

As of September 30, 2016, we had 22,202,465 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 or 701 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.

Our management team may invest or spend the proceeds of our prior offering in ways with which stockholders may not agree or in ways which may not yield a significant return.

Our management will have broad discretion over the use of proceeds from our March 2016 public offering and additional future financings. The intended use of our net proceeds from the March 2016 public offering and sales made though out FBR Sales Agreement is to continue to fund our current Phase 2 trial of HS-410 for the treatment of NMIBC and to advance the current eight patients enrolled in our Phase 1b trial evaluating HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of NSCLC through the reporting of topline data; and the remaining net proceeds will be used for licensing or acquisition of assets complementary to our existing programs, as well as working capital and general corporate purposes. Our management will have considerable discretion in the application of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not improve our operating results or enhance the value of our common stock.

Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.

Until warrant holders acquire shares of our common stock upon exercise of their warrants, the warrant holders will have no rights with respect to shares of our common stock issuable upon exercise of their warrants. Upon exercise of the warrants, the warrant holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The warrants issued in our recent public offering may not have any value.

Each warrant that we issued in our recent public offering will have an exercise price of $1.00 per share and will expire on the fifth anniversary of the original issuance date. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

There is no established market for the warrants issued in our recent public offering to purchase shares of our common stock being offered in this offering.

There is no established trading market for the warrants issued in our recent public offering and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

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

Our shares of common stock are currently listed on The NASDAQ Capital Market. If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder's equity requirement, The NASDAQ Capital Market may take steps to de-list our common stock. Any de-listing would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock when they wish to do so. On May 2, 2016, we received written notice from the Listing Qualifications Department of NASDAQ Stock Market LLC ("NASDAQ") notifying us that for the preceding 30 consecutive business days (March 18, 2016 through April 29, 2016), our common stock did not maintain a minimum closing bid price of $1.00 ("Minimum Bid Price Requirement") per share as required by NASDAQ Listing Rule 5550(a)(2). The notice has no immediate effect on the listing or trading of our common stock which will continue to trade on The NASDAQ Capital Market under the symbol "HTBX." Compliance can be achieved automatically and without further action if the closing bid price of our common stock is at or above $1.00 for a minimum of ten consecutive business days at any time during the 180-day compliance period, in which case NASDAQ will notify us of our compliance and the matter will be closed. From August 2, 2016 through August 15, 2016, our common stock maintained the minimum closing bid price of $1.00 per share and therefore we have regained compliance with the Minimum Bid Price Requirement. However, there can be no assurance that we will be able to continue to maintain compliance with the Minimum Bid Price Requirement if we should in the future fail to be compliant.

In addition, on February 22, 2016, we received a deficiency letter from the NASDAQ indicating that as of December 31, 2015 our stockholders' equity of $2,495,000 did not meet the $2,500,000 minimum required to maintain continued listing. Although the proceeds of our March 2016 offering satisfied the continued listing requirements of the NASDAQ with respect to stockholders' equity, there can be no assurance that we will continue to satisfy such requirements.

In the event of any de-listing, we would take actions to restore our compliance with The NASDAQ Capital Market's listing requirements, but we can provide no assurance that any action taken by us would result in our common stock becoming listed again, or that any such action would stabilize the market price or improve the liquidity of our common stock.

The shares of common stock offered under the FBR Sales Agreement may be sold in "at the market" offerings, and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares that are sold under the FBR Sales Agreement at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price. Investors may experience declines in the value of their shares as a result of share sales made at prices lower than the prices they paid.

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

RECENT SALES OF UNREGISTERED SECURITIES

On September 30, 2016, we issued 7,664 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 Heat 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.

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 Exhibit Index is incorporated herein by reference.

SIGNATURES

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

HEAT BIOLOGICS, INC.

Date: November 10, 2016

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

Date: November 10, 2016

By: /s/ Ann A. Rosar
Ann A. Rosar
Vice President of Finance
(Principal financial and accounting officer)

EXHIBIT INDEX

Exhibit No.	Description
10.1*‡	Exclusive License Agreement (UMIP-114/Strbo) between the University of Miami and Zolovax, Inc., a wholly-owned subsidiary of Heat Biologics effective October 24, 2016
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Vice President of Finance pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Vice President of Finance pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

‡ Confidential treatment has been requested as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

EXHIBIT 10.1

EXCLUSIVE LICENSE AGREEMENT

This License Agreement (the "Agreement") is entered into and made effective as of the last dated signature below (the 'Effective Date") between University of Miami, a Florida not-for-profit corporation, having business offices at 1951 NW 7th Avenue, (C234), Miami, Florida 33136 (" UNIVERSITY") and Zolovax, Inc., a for-profit company organized under the laws of Delaware and wholly owned subsidiary of Heat Biologics, Inc., having business offices at 801 Capitola Drive, Bay 12, Durham, NC 27713 ("LICENSEE"). For purposes of this Agreement, each of UNIVERSITY and LICENSEE may be individually referred to as a 'Party," and collectively referred to as the "Parties."

BACKGROUND

UNIVERSITY has been assigned and owns all rights and title to certain inventions as described in patent application(s) and the UNIVERSITY invention disclosure document in Appendix A. UNIVERSITY wants to have the invention perfected and marketed as soon as possible so that resulting products may be available for public use and benefit. LICENSEE wants to acquire an exclusive license for the Patent Rights for the purposes of making, having made, and sell, using and selling Products and practicing the invention(s) disclosed and claimed in the Patent Rights, in the Territory and in the Field of Use as set forth and defined below.

1. DEFINITIONS

1.1 "Field of Use" shall mean GP96-lg-based vaccines.

1.2 "Net Sales" shall be calculated as set forth in this section, and shall mean gross amounts invoiced by LICENSEE and/or its Sublicensees on commercial sales of Products or use of Process after regulatory approval, if applicable, thereof to third parties (excluding Sublicensees), less deductions for the following, determined in accordance with generally accepted accounting principles:

(a) sales and excise taxes, value added taxes, and duties which fall due and are paid by the purchaser as a direct consequence of such sales and any other governmental charges imposed upon the importation, use or sale of Products, but only to the extent that such taxes and duties are actually included and itemized in the gross sales amounts invoiced to and specifically paid by the purchaser over and above the price of the Products;

(b) trade, quantity and cash discounts actually allowed and taken;

(c) allowances or credits to customers on account of shelf adjustments, failure to supply, rejection, withdrawal, recall or return of Products or on account of retroactive price reductions affecting Products, to the extent that such allowances or credits are actually allowed and taken;

(d) amounts not collectible after reasonable collection efforts;

(e) any charges for freight, postage, shipping or transportation or for shipping insurance;

(f) rebates and charge backs specifically related to Products on an actual credited or paid basis, including those granted to government agencies (such rebates and charge backs to be accrued as an estimate in the month in which the related Products are sold by using generally accepted accounting principles) to the extent that such rebates and charge backs are actually allowed and taken; and,

(g) sales contract administrative fees, fees paid to distributors, wholesaler fees or service charges and other payments to customers or other third parties in connection with the sale of Products, to the extent actually allowed and taken.

1.3 "Patent Rights" shall mean:

(a) the patent application(s) specifically set forth in Appendix A and any United States Patent(s) that issue therefrom or inventions originally disclosed therein or specifically described in the patents and/or any data that subsequently reduces such inventions to practice (including any and all further related provisional applications (i.e. that are subsequently combined with the patent application(s) specifically set forth in Appendix A for conversion to non-provisional application), divisionals, continuations, and continuations-in-part solely to the extent that all of the claims of any such continuations-in-part are wholly supported by the patent application(s) and/or invention disclosure(s) set forth in Appendix A) together with re-examinations or reissue of such United States Patent(s); Parties agree to negotiate in good faith terms and conditions of licensing any improvements on a case by case basis.

(b) any foreign (non-United States) patent applications claiming priority to any patent application(s) specifically set forth in Appendix A and any patents issuing therefrom or on inventions originally disclosed therein or specifically described in the patents (including any and all divisionals, continuations, and continuations-in-part solely to the extent that all of the claims of any such continuations-in-part are wholly supported by the patent application(s) and/or invention disclosure(s) set forth in Appendix A) together with any re examinations or reissue of such foreign patent(s).

1.4 "Product" shall mean any product or part thereof made, used or sold by the LICENSEE or a Sublicensee of the LICENSEE, which:

(a) is covered by (i) an issued, unexpired claim contained in the Patent Rights that has not been revoked or held unenforceable or invalid by a decision of a court or Governmental Authority of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (ii) a pending claim contained in the Patent Rights that has not been pending for more than [*****] years and has not been abandoned, disclaimed, allowed to lapse or finally determined to be unallowable by the applicable government authority in a decision from which no appeal can be taken or from which no appeal is taken within the time allowed for appeal in the country in which any Products is made, used or sold;

(b) is manufactured by using a Process which is covered by (a) an issued, unexpired claim contained in the Patent Rights that has not been revoked or held unenforceable or invalid by a decision of a court or Governmental Authority of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) a pending claim contained in the Patent Rights that has not been pending for more than [*****] years and has not been abandoned, disclaimed, allowed to lapse or finally determined to be unallowable by the applicable government authority in a decision from which no appeal can be taken or from which no appeal is taken within the time allowed for appeal in the country in which any licensed Process is used or in which such Process or portion thereof is used or sold.

1.5 "Process" shall mean any process used by the LICENSEE or a Sublicensee of the LICENSEE which is covered by an issued, unexpired claim or pending claim contained in the Patent Rights.

1.6 "Sublicensee" as used in this Agreement shall mean any third party to whom LICENSEE has granted a license to make, have made, use and/or sell the Product or the Process under the Patent Rights, provided LICENSEE has requested and obtained prior written approval from UNIVERSITY, which approval shall not be unreasonably withheld. Sublicensee shall agree in writing with LICENSEE to accept the conditions and restrictions agreed to by LICENSEE in this Agreement, and LICENSEE shall, within thirty (30) days of request by UNIVERSITY, provide to UNIVERSITY a fully signed, non-redacted copy of each agreement executed by a Sublicensee, with all exhibits, appendixes, attachments and any amendments thereto, as applicable.

1.7 "Territory" shall mean the world.

1.8 "Technology" means the "Patent Rights" and additional technology, information, or other materials that will be provided by UNIVERSITY to LICENSEE, at LICENSEE's expense. Technology may or may not be confidential in nature.

2. GRANT

2.1 UNIVERSITY hereby grants to LICENSEE and LICENSEE hereby accepts an exclusive license, subject to any rights of the government in the Territory for the Field of Use, with the right to sublicense, under the Patent Rights and a nonexclusive license to the know-how developed as of Effective Date by Natasa Strbo and Laura Romero (the "Inventors") that is not encumbered by any third party rights, which is necessary to practice the Patent Rights to research, develop, make, have made, use, commercialize, market, promote, distribute, export, sell, offer to sell , or otherwise offer to dispose of Products in the Field of Use in the Territory and import the Product(s) and to practice the Process(es) described and/or claimed in the Patent Rights.

2.2 UNIVERSITY retains a non-sublicensable, non-exclusive, royalty-free, perpetual, irrevocable, worldwide right to make and to use the subject matter described and/or claimed in the Patent Rights for non-commercial, internal research, or educational purposes. Further, the United States Government may also have certain rights, title and/or interest in/to the licensed patent(s) and/or patent application(s), including but not limited to the rights to use the licensed patent(s) and/or patent application(s) for internal, non-commercial and educational purposes only.

2.3 Subject to a third party's rights, LICENSEE shall have the right of first negotiation to future patent(s) and patent application(s) the practice of which would infringe at least one claim within the "Patent Rights", which is developed from the Inventors' laboratory owned or controlled by UNIVERSITY.

3. ROYALTIES AND OTHER CONSIDERATION

3.1 In consideration of the license herein granted, LICENSEE shall pay fees and royalties to UNIVERSITY as follows:

(a) License issue fee of $[*****]) is due to UNIVERSITY within sixty (60) days of the Effective Date of this Agreement.

(b) Past patent expenses incurred by UNIVERSITY in the amounts and at the times as set forth in Appendix B.

(c) Running royalty in an amount equal to [*****] of the annual Net Sales of the Product(s) leased or sold by or for LICENSEE or its Sublicensees ("Running Royalty"), subject

to reduction as set forth in the next sentence. In the event LICENSEE is required to pay royalties to a third party or third parties for the same Product or Process as licensed under this Agreement, then LICENSEE may reduce the Running Royalty by [*****] for each one dollar ($1.00) in royalties which LICENSEE is obligated to pay to a third party or third parties under such licenses, provided however, that the royalties payable to UNIVERSITY under this section shall not be reduced to less than [*****] of annual Net Sales of the Product(s) leased or sold by or for LICENSEE or its Sublicensees. If, in any one calendar year, LICENSEE is not able to fully recover its [*****] portion of the payments due to a third party, it shall be entitled to carry forward such right of off-set to future calendar years with respect to the excess amount. [*****].

However, the parties agree that Licensee may only apply one of the aforementioned (i) royalty rate reduction of not less than [*****] of annual Net Sales or (ii) Combination Product reduction of Net Sales, as described above, at Licensee's option. For clarity, Licensee may either apply a royalty rate reduction in connection with royalties to a third party or third parties or a Combination Product reduction of Net Sales, as described above. In any event, the royalty rate shall not be less than [*****].

(d) By the first (1st) day of each anniversary of the Effective Date and until expiration or termination of this Agreement, LICENSEE agrees to pay UNIVERSITY an annual fee of:

(i) [*****] on the third (3rd) and fourth (4th) anniversaries;

(ii) [*****] on the fifth (5th) and sixth (6th) anniversaries;

(iii) [*****] on the seventh (7th) and eighth (8th) anniversary;

(iv) [*****] on the ninth (9th) and tenth (10th) anniversaries; and

(v) [*****] on the eleventh (11th) anniversary and every anniversary thereafter. This amount shall be decreased by [*****] in the event that clinical trials are ongoing but regulatory authority approval has not been granted, despite best efforts on part of LICENSEE.

Such annual fees are creditable towards any other consideration, including royalty and milestone payments that are, as set forth herein, due to the UNIVERSITY by LICENSEE.

(e) Royalties are payable on a country-by-country basis beginning on the date of first commercial sale and ending on expiration of the last to expire Patent Rights in such country.

3.2 All payments hereunder shall be made in U.S. dollars.

3.3 In the event that any taxes, withholding or otherwise, are levied by any taxing authority in connection with accrual or payment of any royalties payable to UNIVERSITY under this Agreement, the LICENSEE shall be solely responsible to pay such taxes to the local tax authorities on behalf of UNIVERSITY, as a nonprofit, tax-exempt organization as defined in Section 501(c)(3) of the Internal Revenue Code. Should LICENSEE be required under any law or regulation of any government entity or authority to withhold or deduct any portion of the payments on royalties due to UNIVERSITY, then the sum payable to UNIVERSITY shall be increased by the amount necessary to yield to UNIVERSITY an amount equal to the sum it would have received had no withholdings or deductions been made. UNIVERSITY shall cooperate reasonably with LICENSEE in the event LICENSEE elects to assert, at its own expense, any exemption from any such tax or deduction.

3.4 SUBLICENSING: If LICENSEE receives any fees, minimum royalties, equity ownership, securities, or other payments in consideration for any rights granted under a sublicense of the Patent Rights, and such payments are not based directly upon the amount or value of Products or Processes sold by the Sublicensee nor represent payment of costs to LICENSEE for a development program which LICENSEE is obligated to perform under such sublicense, then LICENSEE shall pay UNIVERSITY [*****] of such payments; provided that this [*****]shall not apply to royalty payments on Net Sales of Product, which shall be calculated as described in Section 3.1.(c) or amounts paid for purchase of securities of LICENSEE to the extent such payment does not exceed the fair market value of such securities.

3.5 Notwithstanding the Sublicensee's payment obligation to LICENSEE, LICENSEE shall be directly responsible for all royalties and payments due pursuant to this section 3.

4. COMMERCIAL DILIGENCE AND MILESTONES

4.1 LICENSEE shall use commercially reasonable efforts to develop, manufacture, market and sell Product in the Territory and will exert commercially reasonable efforts to create a demand for Product.

4.2 LICENSEE agrees to submit annual reports, as to its efforts to develop Product and markets for Product. Such reports shall include assurance by LICENSEE of its intent to actively develop commercial embodiments of the Patent Rights and a summary of its efforts in this regard.

4.3 LICENSEE, at its sole expense, shall make commercially reasonable efforts to accomplish the following:

(a) by the first day of the [*****] anniversary of Effective Date, pre-IND meeting with FDA (or correlate submission to regulatory organization in other country);

(b) by the first day of the [*****] anniversary of Effective Date, IND submission to FDA (or correlate submission to regulatory organization in other country); and

(c) by the first day of the [*****] anniversary of Effective Date, first subject treated in a phase I clinical trial

(d) LICENSEE, upon written request to UNIVERSITY, may be granted an extension of one or more of the above milestones (a)-(c) by six (6) months up to three (3) times for a total possible extension of eighteen (18) months provided LICENSEE pays UNIVERSITY a payment of a [*****] fee per extension. If LICENSEE extends a particular milestone, all subsequent milestones will be extended by the same time period.

(e) The Parties agree to the following milestones and payments but not more than once even if the milestone is accomplished for more than one Product in the Territory. For the avoidance of doubt, if the same milestone is achieved by a Sublicensee of the Patent Rights, then UNIVERSITY shall share in any payments LICENSEE receives from a Sublicensee according to section 3.4 above, and the following milestones and payments will not be due. The following milestone payments shall not be creditable towards any other monies UNIVERSITY is due from LICENSEE, including but not limited to: payment of past patent costs, payment of future patent costs, royalty payments, and royalty payments associated with a Sublicensee's sale of any Product(s):

(f) Upon dosing of the first patient in the first phase I clinical trial conducted by Licensee based upon the Patent Rights in the Field of Use, LICENSEE shall pay UNIVERSITY an additional amount of [*****]

(g) Upon dosing of the first patient in the first phase II clinical trial conducted by Licensee based upon the Patent Rights in the Field of Use, LICENSEE shall pay UNIVERSITY an additional amount of [*****]

(h) Upon dosing of the first patient in the first phase III clinical trial conducted by Licensee based upon the Patent Rights in the Field of Use, LICENSEE shall pay UNIVERSITY an additional amount of [*****]

(i) Upon receiving marketing approval by the first regulatory authority for the first product developed by Licensee based upon the Patent Rights in the Field of Use, LICENSEE shall pay UNIVERISTY an additional amount of [*****]

4.4 In the event that either Party is prevented from performing under the Agreement as a result of an act of God, hurricane, war, or terrorism, any delays in or failure of performance under the Agreement shall be excused if and to the extent that such delays or failures are beyond such Party's reasonable control. UNIVERSITY and LICENSEE shall notify the other promptly upon learning of any event that may result in any delay or failure to perform. If the force majeure event occurs and continues to prevent substantial performance for more than ninety (90) days the other Party has the right to terminate this Agreement.

4.5 [*****]

5. **SPONSORED RESEARCH**. LICENSEE will in good faith negotiate with the UNIVERSITY Office of Research Administration to have UNIVERSITY conduct certain preclinical proof of concept studies that will be required for partnering the licensed Patent Rights and which LICENSEE believes are best performed by the UNIVERSITY. The result of these negotiations will be memorialized in a separate agreement signed by both Parties.

6. **TERM**. The term of this Agreement shall commence on the Effective Date and shall remain in effect until the date on which all issued patents and filed patent applications within the Patent Rights have expired or been abandoned and no royalties are due pursuant to section 3, unless this Agreement is terminated earlier in accordance with any of the other provisions of section 15.1. For the purposes of clarity, after the expiration of the last to expire Patent Rights in such country, LICENSEE shall retain a fully-paid-up, royalty free and irrevocable license to practice such Patent Rights in such country.

7. UNITED STATES LAWS

7.1 LICENSEE understands that the Patent Rights may have been developed under a funding agreement with the Government of the United States of America and, if so, that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to the Government's rights under any agreement and any applicable law or regulation. If there is a conflict between an agreement, applicable law or regulation and this Agreement, the terms of the Government agreement, applicable law or regulation shall prevail. Specifically, this Agreement is subject to all of the terms and conditions of Title 35 United States Code Sections 200 through 212 (to the extent applicable), including an obligation that Product(s) sold or produced in the United States be "manufactured substantially in the United States," and LICENSEE agrees to take all reasonable action necessary on its part as licensee to enable UNIVERSITY to satisfy its obligation thereunder, relating to the Patent Rights.

7.2 It is understood that UNIVERSITY and LICENSEE are subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the Export Administration Act of 1979), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by LICENSEE that LICENSEE shall not export data or commodities to certain foreign countries without prior approval of such agency. UNIVERSITY neither represents that a license shall or shall not be required nor that, if required, it shall be issued. LICENSEE represents and warrants that it will comply with, and will cause its Sublicensees to comply with all United States export control laws, rules and regulations. LICENSEE is solely responsible for any violation of such laws and regulations by itself or its Sublicensees, and it will indemnify, defend and hold UNIVERSITY harmless for the consequences of any such violation.

8. PATENT PROTECTION

8.1 Licensee shall pay for one hundred percent (100%) of the costs of patent preparation, prosecution and maintenance after the Effective Date, including all interferences, reissues, re examinations, oppositions or requests for patent term extensions. LICENSEE shall reimburse UNIVERSITY one hundred percent (100%) of third party expenses incurred by and paid for by UNIVERSITY in seeking and securing the Patent Rights prior to the Effective Date, according to the schedule set forth in Appendix B.

8.2 Subject to UNIVERSITY's authority, LICENSEE, during the term of this Agreement, is responsible for the prosecution, maintenance and enforcement of the Patent Rights in UNIVERSITY's name, for UNIVERSITY's benefit, whereby LICENSEE: (a) shall keep UNIVERSITY informed in writing of all material actions taken in this regard to permit UNIVERSITY an opportunity to review and comment thereon (b) shall consider in good faith, take into account and implement the reasonable comments made by UNIVERSITY, (c) shall not add inventors who do not have an obligation to assign their ownership interest to the UNIVERSITY to any patent or patent application among the Patent Rights without the permission of UNIVERSITY, (d) shall not abandon prosecution of any pending patent applications or fail to maintain issued patents without providing UNIVERSITY the opportunity to assume control of prosecution and maintenance of the Patent Rights as provided below, and (e) shall notify UNIVERSITY no less than forty-five (45) days where reasonably practical prior to any deadline for action set forth by the US Patent and Trademark Office or its foreign counterparts (a "Patent Office") and promptly if not reasonably practical. In the event LICENSEE desires to abandon prosecution or

maintenance of any Patent Rights filed in a particular country, LICENSEE shall provide UNIVERSITY with no less than sixty (60) days written notice prior to the Patent Office deadline for action in which LICENSEE shall document: (i) the patent/patent application number; (ii) the patent/patent application title; (iii) the country in which such patent/patent applications is issued/pending. Unless otherwise agreed to by the Parties, upon UNIVERSITY's receipt of such written notice, any and all rights granted to LICENSEE by UNIVERSITY to said patent/patent application in said country shall promptly terminate. For clarity, upon such termination of rights under such patent/patent application, UNIVERSITY shall be free to license, sell, assign, dispose of, and/or take any other action with respect to the rights to said patent/patent application at its sole and absolute discretion and with no obligation to LICENSEE. UNIVERSITY shall provide to LICENSEE reasonable assistance in the prosecution, maintenance and enforcement of the Patent Rights, at LICENSEE's request and expense.

8.3 Upon learning of any infringement of Patent Rights by third parties in any country, LICENSEE and UNIVERSITY will promptly inform each other, as the case may be, in writing of that fact and will supply the other with any available evidence pertaining to the infringement. LICENSEE, at its own expense, shall have the option to take whatever steps are necessary to stop the infringement at its expense and recover damages and will be entitled to retain all damages so recovered. If LICENSEE brings suit against an alleged infringer and UNIVERSITY is a necessary party to such suit, UNIVERSITY agrees to be named in such suit at LICENSEE's expense. In the event that UNIVERSITY and LICENSEE mutually agree to bring suit, costs and expenses shall be shared equally and any recovery in excess of expenses shall be shared equally. In any event, no settlement, consent, judgment or other voluntary final disposition of the suit that would materially or adversely affect the interests of the UNIVERSITY may be entered into without the consent of UNIVERSITY. In the event LICENSEE does not take steps to stop the infringement within ninety (90) days after notice of same by either Party, UNIVERSITY shall have the right to take whatever steps it deems necessary to stop the infringement at its expense and recover damages therefore, and will be entitled to retain all damages so recovered. Each Party shall provide to the Party enforcing any Patent Rights reasonable assistance in such enforcement, at such enforcing Party's request and expense.

9. INDEMNIFICATION AND LIMITATION OF LIABILITY

9.1 LICENSEE will defend, indemnify and hold harmless the UNIVERSITY, its trustees, officers, faculty, employees and students ("University lndemnitees") against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including attorney's fees through the appellate levels) (collectively "Liabilities") which may be brought against University Indemnities by third parties as a result of or arising out of: (a) any negligent act or omission of LICENSEE, its Sublicensees, or its or their agents or employees, or (b) the use, production, manufacture, sale, lease, consumption or advertisement by LICENSEE, its Sublicensees or its or their agents or employees of any Products; provided, however, LICENSEE shall not indemnify or hold harmless any University lndemnitee from any Liabilities to the extent that such Liabilities are finally determined to have resulted from the willful negligent acts or omissions of such University lndemnitee.

9.2 LICENSEE will defend, indemnify and hold harmless the University Indemnities against any and all judgments and damages arising from any and all third party claims of infringement which may be asserted against University Indemnities because of the manufacture, use, promotion and sale of Products. LICENSEE will bear all costs and expenses incurred in connection with the defense of any such claims or as a result of any settlement made or judgment rendered on the

basis of such claims. LICENSEE agrees to provide attorneys which shall be approved by University Indemnities at their sole and absolute discretion to defend against any actions brought or filed against any University lndemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought; provided, however, that any University lndemnitee shall have the right to retain its own counsel, at the reasonable expense of LICENSEE, if representation of such University lndemnitee by counsel retained by LICENSEE would be inappropriate because of conflict of interests or otherwise. LICENSEE agrees to keep UNIVERSITY informed of the progress in the defense and disposition of such claim, and to consult with UNIVERSITY prior to any proposed settlement.

9.3 UNIVERSITY shall have no further liability to LICENSEE for any loss or damages LICENSEE may incur as a result of the invalidity of UNIVERSITY's Patent Rights.

9.4 UNIVERSITY shall have no responsibility with respect to LICENSEE's own trademarks and trade name, and LICENSEE in respect to the use thereof will defend, indemnify and hold harmless UNIVERSITY against any and all third party claims.

9.5 UNIVERSITY is not liable for any special, consequential, lost profit, expectation, punitive or other indirect damages in connection with any claim arising out of or related to this Agreement, whether grounded in tort (including negligence), strict liability, contract, or otherwise.

9.6 This Agreement to reimburse and indemnify under the circumstances set forth above shall continue after the expiration or termination of this Agreement.

10. WARRANTIES. UNIVERSITY MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AND HEREBY DISCLAIMS ALL SUCH WARRANTIES, AS TO ANY MATIER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE CONDITION OF ANY INVENTION (S) OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, LICENSED UNDER THIS AGREEMENT; OR THE MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE INVENTION OR PRODUCT; OR THAT THE USE OF THE LICENSED PRODUCT WILL NOT INFRINGE ANY PATENTS, COPYRIGHTS, TRADEMARKS, OR OTHER RIGHTS; PROVIDED HOWEVER, UNIVERSITY WARRANTS THAT IT HAS NOT LICENSED THE PATENT RIGHTS TO ANY THIRD PARTY.

11. REPORTS AND RECORDS

11.1 Prior to first Net Sale, LICENSEE agrees to provide UNIVERSITY with an annual written report specifying the progress of research, development, and marketing activities. Commencing with the first (1^{st}) calendar quarter after the first Net Sale, the LICENSEE shall provide to UNIVERSITY a written report specifying during the preceding calendar quarter (a) the number or amount of Products sold hereunder by LICENSEE and its Sublicensees, (b) the total billings for all Product(s) sold, (c) deductions as applicable to calculate Net Sales, (d) total royalties due, (e) names and addresses of all Sublicensees. Such reports shall be due within fifty (5O) days following the last day of each calendar quarter in each year during the term of this Agreement. Each such report shall be accompanied by payment in full of the amount due UNIVERSITY in United States dollars.

11.2 For a period of three (3) years from the date of each report pursuant to section 11.1, LICENSEE, shall keep records adequate to verify each such report and accompanying payment made to UNIVERSITY under this Agreement, and an independent Certified Public Accountant or Accounting Firm selected by UNIVERSITY and acceptable to LICENSEE may have access, on reasonable notice during regular business hours, not to exceed twice per year, to such records to verify such reports and payments. LICENSEE's acceptance of UNIVERSITY's selection of said Certified Public Accountant or Accounting firm shall not be unreasonably withheld. Such Accountant or Accounting Firm shall not disclose to UNIVERSITY any information other than that

information relating solely to the accuracy of, or necessity for, the reports and payments made hereunder and shall sign LICENSEE'S standard confidentiality agreement prior to obtaining access to any records. The fees and expense of the Certified Public Accountant or Accounting Firm performing such verification shall be borne by UNIVERSITY unless in the event that the audit reveals an underpayment of royalty or sublicensing fees by more than five (5%) percent, in which case the cost of the audit shall be paid by LICENSEE.

12. MARKING AND STANDARDS

12.1 LICENSEE agrees to mark and have its Sublicensees mark any and all Products (or their containers or labels) that are made, sold, or otherwise disposed of by LICENSEE or Sublicensees under the license granted in this Agreement, in accordance with and to the extent required by the applicable patent marking statute; provided that LICENSEE does not need to mark Products (or their containers or labels) if such Products are used solely for LICENSEE's own internal research purposes and/or used for validation studies on LICENSEE's behalf.

12.2 LICENSEE shall act in good faith to maintain satisfactory standards in respect to the nature of the Product manufactured and/or sold by LICENSEE. LICENSEE, shall act in good faith to ensure that all Products manufactured and/or sold by it shall be of a quality which is appropriate to Products of the type here involved. LICENSEE agrees that similar provisions shall be included by sublicenses of all tiers.

13. ASSIGNMENT

13.1 Permitted Assignment. LICENSEE may assign or delegate its rights or obligations under this Agreement only under the following circumstances:

(a) By providing UNIVERSITY with written notice of the proposed assignment, including the proposed assignee's contact information, at least thirty (30) days prior to the date of assignment, and obtaining UNIVERSITY's express written consent to the proposed assignment, which consent shall not be unreasonably withheld; or

(b) As part of a sale or change of control, regardless of whether such a sale or change of control occurs through an asset sale, stock sale, merger or other combination, or any other transfer of: (i) LICENSEE's entire or substantially all of the business; or (ii) that part of LICENSEE's business that exercises all rights granted under this Agreement.

13.2 Conditions of Assignment. Prior to any assignment, (i) the proposed assignee must agree in writing to UNIVERSITY to be bound by this Agreement, and (ii) LICENSEE must pay UNIVERSITY an assignment fee in the amount of [*****] due within thirty (30) days of assignment agreement execution. [*****]

13.3 Any Other Assignment by Licensee. Any attempt by LICENSEE to assign this Agreement that fails to comply with Section 13.1and 13.2 are null and void.

14. NOTICE. Any notice, payment, report or other correspondence (hereinafter collectively referred to as "correspondence") required or permitted to be given hereunder shall be mailed by certified mail or delivered by hand to the Party to whom such correspondence is required or permitted to be given hereunder. If mailed, any such notice shall be deemed to have been given when mailed as evidenced by the postmark at point of mailing. If delivered by hand, any such correspondence shall be deemed to have been given when received by the Party to whom such correspondence is given, as evidenced by written and dated receipt of the receiving Party.

All correspondence to LICENSEE shall be addressed as follows:

Chief Executive Officer
Zolovax, Inc.
801 Capitola Drive, Bay 12
Durham, NC 27713

All correspondence to UNIVERSITY shall be addressed, in duplicate, as follows:

FOR NOTICE:

Assistant Vice President
Financial Operations University of Miami
1320 South Dixie Highway, Suite 1230
Gables One Tower
Coral Gables, FL 33146

WITH A COPY TO:

Office of the General Counsel
University of Miami
1320 South Dixie Highway, Suite 1250
Gables One Tower
Coral Gables, FL 33146

FOR NOTICE AND PAYMENT:

Office of Technology Transfer
University of Miami
1951 NW 7th Avenue, Suite 300
Miami, FL 33136

Either Party may change the address to which correspondence to it is to be addressed by notification as provided herein.

15. MISCELLANEOUS PROVISIONS

15.1 TERMINATION

(a) LICENSEE shall have the right to terminate this Agreement upon sixty (60) days prior written notice to UNIVERSITY. Such termination will not relieve Licensee of Licensee's obligation to pay any royalties or license fees owed at the time of such termination.

(b) UNIVERSITY and LICENSEE shall have the right to terminate this Agreement if the other Party commits a material breach of an obligation under this Agreement and fails to cure any such breach within thirty (30) days of receipt of written notice from non-breaching Party. A material breach shall include but not be limited to the following: (a) failure to deliver to UNIVERSITY any payment at the time such payment is due under this Agreement, (b) failure to meet or achieve milestone schedule, (c) failure to possess and maintain required insurance coverage. UNIVERSITY shall have the right to terminate this Agreement in the event LICENSEE provides a false report and continues in default for more than thirty (30) days after receiving written notice of such default or false report. Such termination shall be effective upon further written notice to the breaching Party after failure by the breaching

Party to cure. If UNIVERSITY commits a material breach or defaults, then LICENSEE has no duty to continue the payment of royalties as set forth in section 3 of this Agreement.

(c) The license and rights granted in this Agreement have been granted on the basis of the special capability of LICENSEE to perform research and development work leading to the manufacture and marketing of the Product(s). Accordingly, LICENSEE covenants and agrees that in the event any proceedings under the Bankruptcy Act or any amendment thereto, be commenced by or against LICENSEE, and, if against LICENSEE, said proceedings shall not be dismissed with prejudice before either an adjudication in bankruptcy or the confirmation of a composition, arrangement, or plan of reorganization, or in the event LICENSEE shall be adjudged insolvent or make an assignment for the benefit of its creditors, or if a writ of attachment or execution be levied upon the license hereby created and not be released or satisfied within ten (10) days thereafter, or if a receiver be appointed in any proceeding or action to which LICENSEE is a party with authority to exercise any of the rights or privileges granted hereunder and such receiver be so discharged within a period of forty-five (45) days after his appointment, any such event shall be deemed to constitute a breach of this Agreement by LICENSEE and, UNIVERSITY, at the election of UNIVERSITY, but not otherwise, ipso facto, and without notice or other action by UNIVERSITY, shall terminate this Agreement and all rights of LICENSEE hereunder and all rights of any and all persons claiming under LICENSEE.

(d) Any termination of this Agreement shall be without prejudice to UNIVERSITY's right to recover all amounts accruing to UNIVERSITY prior to such termination and cancellation. Except as otherwise provided, should this Agreement be terminated for any reason, LICENSEE shall have no rights, express or implied, under any intellectual property rights which are the subject matter of this Agreement, nor have the right to recover any royalties paid UNIVERSITY hereunder. Upon termination, LICENSEE shall have the right to dispose of Products then in their possession and to complete existing contracts for such Products, so long as contracts are completed within six (6) months from the date of termination, subject to the payment of royalties to UNIVERSITY as provided in section 3 hereof. Failure to terminate on any basis shall not prejudice or impact the UNIVERSITY's rights and ability to subsequently terminate for the same or a related basis.

15.2 INSURANCE

(a) Prior to the commencement of clinical trials, LICENSEE must maintain commercial general liability insurance in the amounts of not less than One Million Dollars ($1,000,000) per incident and $1,000,000 annual aggregate. After the commencement of the first clinical trial for the first Product but prior to the first commercial sale of a Licensed Product, LICENSEE must maintain commercial general liability insurance of not less than One Million Dollars ($1,000,000) per incident and clinical trials liability insurance of not less than Three Million Dollars ($3,000,000). After the first commercial sale of a Product, LICENSEE must maintain commercial general liability insurance in the amounts of not less than Three Million Dollars ($3,000,000) per incident and Five Million Dollars ($5,000,000) annual aggregate. Immediately prior to the commencement of the first clinical trial for the first Product, UNIVERSITY, its employees and agents, will be named as additional insured. After the first commercial sale of a Product, LICENSEE shall maintain products liability/completed operations and clinical trials insurance coverage in the amount of Ten Million Dollars ($10,000,000).

(b) LICENSEE shall not cancel such insurance without thirty (30) days prior notice to UNIVERSITY. Such cancellation without replacement insurance being obtained shall be cause for termination.

(c) The terms of this provision shall extend beyond termination of the agreement.

15.3 USE OF NAME. LICENSEE shall not use the name of the University of Miami, or any of its trustees, faculty, students or employees, or any adaptation thereof, in any publication, including advertising, promotional or sales literature without the prior written consent of Mr. Humberto M. Speziani, Assistant Vice President, Financial Operations, 1320 South Dixie Highway, Suite 1230, Gables One Tower, Coral Gables, FL 33146.

15.4 GOVERNING LAW. This Agreement shall be considered as having been entered into in the State of Florida, United States of America, and shall be construed and interpreted in accordance with the laws of the State of Florida. In any action or proceeding arising out of or relating to this Agreement (an "Action"), each of the Parties hereby irrevocably submits to the jurisdiction of any federal or state court sitting in Miami, Florida, and further agrees that any Action shall be heard and determined in such Florida federal court or in such state court. Each Party hereby irrevocably waives, to the fullest extent it may effectively do so, the defense of an inconvenient forum to the maintenance of any Action in Miami, Florida.

15.5 CAPTIONS. The captions and section headings of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

15.6 SEVERABILITY. Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provision shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such part or provision in valid and enforceable manner, and the remainder of the Agreement shall remain binding upon the Parties hereto.

15.7 SURVIVAL

(a) The provisions of section 1, 7, 9, 10, 12, 14, 15.3, 15.4, 15.9 and 15.13 shall survive the termination or expiration of this Agreement and shall remain in full force and effect.

(b) The provisions of this Agreement which do not survive termination or expiration hereof (as the case may be) shall, nonetheless, be controlling on, and shall be used in construing and interpreting, the rights and obligations of the Parties hereto with regard to any dispute, controversy or claim which may arise under, out of, in connection with, or relating to this Agreement.

(c) Sublicenses in good standing shall survive termination of this license as a direct license from UNIVERSITY, provided that Sublicensees assume the obligations set forth in the definitive agreement. UNIVERSITY will enter into a direct agreement with such Sublicensees upon LICENSEE's written request.

15.8 AMENDMENT. No amendment or modification of the terms of this Agreement shall be binding on either Party unless reduced to writing and signed by an authorized officer of the Party to be bound.

15.9 NON-WAIVER. No failure or delay on the part of a Party in exercising any right hereunder will operate as a waiver of, or impair, any such right. No waiver of any of the provisions of this Agreement shall be effective unless it is in writing, and signed by the Party against whom it is asserted, and any such written waiver shall only be applicable to the specific instance to which it

relates and shall not be deemed to be a continuing or future waiver. No single or partial exercise of any such right will preclude any other or further exercise thereof or the exercise of any other right. No waiver of any such right will be deemed a waiver of any other right hereunder.

15.10 INDEPENDENT CONTRACTOR RELATIONSHIP. This Agreement is not intended to create nor shall be construed to create any relationship between LICENSEE and UNIVERSITY other than that of independent entities contracting for the purpose of effecting provisions of this Agreement. It is further expressly agreed that no work, act, commission or omission of any Party, its agents, servants or employees, pursuant to the terms and conditions of this Agreement, shall be construed to make or render any Party, its agents, servants or employees, an agent, servant, representative, or employee of, or joint venturer with, the other Party. Neither Party shall have any right to bind or obligate the other Party in any way nor shall it represent that it has any right to do so.

15.11 REPRESENTATION BY COUNSEL. Each Party acknowledges that it has had the opportunity to be represented by counsel of such Party's choice with respect to this Agreement. In view of the foregoing and notwithstanding any otherwise applicable principles of construction or interpretation, this Agreement shall be deemed to have been drafted jointly by the Parties and in the event of any ambiguity, shall not be construed or interpreted against the drafting Party.

15.12 NO THIRD PARTY BENEFICIARIES. No third persons or entities are intended to be or are third party beneficiaries of or under this Agreement, including, without limitation, Sublicensees. Nothing in this Agreement shall be construed to create any liability on the part of the Parties or their respective directors, officers, shareholders, employees or agents, as the case may be, to any such third parties for any act or failure to act of any Party hereto.

15.13 CONFIDENTIALITY. Parties shall hold each other's Confidential Information in confidence and shall not disclose Confidential Information to any third party without each other's prior written consent. "Confidential Information" means any information disclosed by Party that is not generally known to the public or, by its nature, should be reasonably considered confidential. The Parties acknowledge and agree that a breach of this section would cause irreparable harm and that either Party shall be entitled to seek equitable relief from such breach without the obligation of posting a bond or proving actual damages.

The Parties agree to keep the terms of this Agreement confidential provided that each Party may disclose this Agreement to its authorized agents and investors who are bound by similar confidentiality provisions and to the extent required by law.

15.14 ENTIRE AGREEMENT. This Agreement constitutes the entire agreement between the Parties hereto respecting the subject matter hereof, and supersedes and terminates all prior agreements respecting the subject matter hereof, whether written or oral, and may be amended only by an instrument in writing executed by both Parties hereto.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their respective officers thereunto duly authorized to be effective as of the Effective Date.

ZOLOVAX, INC.		UNIVERSITY	
	October 24, 2016		11 Oct K
Signature	Date	Signature	Date
Jeffrey Wolf		James O'Connell	
Printed Name		Printed Name	
CEO		Director, Office of Technology Transfer University of Miami 1951 NW 7th Avenue, Suite 310 Miami, Florida 33136 United States of America	
Printed Title		Printed Title	

APPENDIX A
TECHNOLOGIES/INTELLECTUAL PROPERTY

To include Patents:

- Provisional patent application entitled: "VECTORS AND VACCINE CELLS FOR IMMUNITY AGAINST ZIKA VIRUS" and filed 11-0ct-2016 with the US Patent and Trademark Office and assigned application number 62/406,506.

APPENDIX B
SUMMARY OF CURRENT OUTSTANDING PATENT COSTS

UM Technology Number	Current Outstanding Balance	Payment terms: Outstanding patent
UMIP-114	[*****]	N A

As of the Effective Date, the UNIVERSITY has not received invoices related to the preparation and filing of the provisional patent application listed within Appendix A. LICENSEE agrees that the costs relating to this work shall be considered as costs incurred during the term of this Agreement and shall be payable as per Section 8.2. This cost to prepare and file the provisional patent is estimated to not exceed [*****].

EXHIBIT 31.1

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

I, Jeffrey Wolf, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2016

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

EXHIBIT 31.2

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

I, Ann Rosar, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2016

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

EXHIBIT 32.1

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

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

(1) the accompanying Quarterly Report on Form 10-Q of the Registrant for the quarter ended September 30, 2016 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: November 10, 2016

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

EXHIBIT 32.2

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

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

(1) the accompanying Quarterly Report on Form 10-Q of the Registrant for the quarter ended September 30, 2016 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: November 10, 2016

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