VALHI INC /DE/
Form 4
April 15, 2003

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

FORM 4
STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP

[ ] Check this box if no longer subject to Section 16.
Form 4 or Form 5 obligations may continue.

1. Name and Address of Reporting Person(s)
Contran Corporation
Three Lincoln Centre
5430 LBJ Freeway, Suite 1700
Dallas, TX 75240

2. Issuer Name and Ticker or Trading Symbol
Valhi, Inc. (VHI)

3. I.R.S. Identification Number of Reporting Person, if an entity (Voluntary)

4. Statement for Month/Day/Year
04/11/2003

5. If Amendment, Date of Original (Month/Day/Year)

6. Relationship of Reporting Person(s) to Issuer (Check all applicable)
[ ] Director [X] 10% Owner
[ ] Officer (give title below) [ ] Other (specify below)

7. Individual or Joint/Group Filing (Check Applicable Line)
[X] Form filed by One Reporting Person
[ ] Form filed by More than One Reporting Person

Table I Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1)Title of Security	2)Transaction Date (Month/Day/Year)	3.Transaction Code		4.Securities Acquired(A) or Disposed of (D)		
		Code	V	Amount	A or D	Price
Common Stock $.01 par value	04/11/03	P		5,000	A	$10.7000
Common Stock $.01 par value	04/11/03	P		1,400	A	$10.6500
Common Stock $.01 par value						
Common Stock $.01 par value						
Common Stock $.01 par value						

Table II (PART 1) Derivative Securities Acquired, Disposed of, or Beneficially Owned (Columns 1

1)Title of Derivative Security	2)Conversion or Exercise Price of Derivative Security	3)Transaction Date	4)Transaction Code		5)Number of Derivative Securities Acquired (A) or Disposed of (D)	
			Code	V	A	D

Table II (PART 2) Derivative Securities Acquired, Disposed of, or Beneficially Owned (Columns 1

1)Title of Derivative Security	3)Transaction	7)Title and Amount of Underlying	8)Price of Deri-

	Date	Securities		vative
		Title	Amount or Number of Shares	Security

Explanation of Responses:

(1) Directly held by the Contran Deferred Compensation Trust No. 2. See Additional Information below for a description of the relationship.

(2) Directly held by National City Lines, Inc. See Additional Information below for a description of the relationship.

(3) Directly held by Valhi Group, Inc. See Additional Information below for a description of the relationship.

Additional Information

Valhi Group, Inc, ("VGI"), National City Lines, Inc. ("National"), Contran Corporation ("Contran"), the Harold Simmons Foundation, Inc. (the "Foundation"), the Contran Deferred Compensation Trust No. 2 (the "CDCT No. 2") and The Combined Master Retirement Trust (the "CMRT") are the direct holders of approximately 77.6%, 9.1%, 2.9%, 1.3%, 0.4% and 0.1%, respectively, of the outstanding common stock of Valhi, Inc. ("Valhi"). National, NOA, Inc. ("NOA") and Dixie Holding Company ("Dixie Holding") are the direct holders of approximately 73.3%, 11.4% and 15.3%, respectively, of the outstanding common stock of VGI. Contran and NOA are the direct holders of approximately 85.7% and 14.3%, respectively, of the outstanding common stock of National. Contran and Southwest Louisiana Land Company, Inc. ("Southwest") are the direct holders of approximately 49.9% and 50.1%, respectively, of the outstanding common stock of NOA. Dixie Rice Agricultural Corporation, Inc. ("Dixie Rice") is the direct holder of 100% of the outstanding common stock of Dixie Holding. Contran is the holder of 100% of the outstanding common stock of Dixie Rice and approximately 88.9% of the outstanding common stock of Southwest.

Substantially all of Contran's outstanding voting stock is held by trusts established for the benefit of certain children and grandchildren of Harold C. Simmons (the "Trusts"), of which Mr. Simmons is the sole trustee. As sole trustee of each of the Trusts, Mr. Simmons has the power to vote and direct the disposition of the shares of Contran stock held by each of the Trusts. Mr. Simmons, however, disclaims beneficial ownership of any shares of Contran stock that the Trusts hold.

The Foundation directly holds approximately 1.3% of the outstanding Valhi common stock. The Foundation is a tax-exempt foundation organized for charitable purposes. Harold C. Simmons is the chairman of the board of the Foundation and may be deemed to control the Foundation.

The CDCT No. 2 directly holds approximately 0.4% of the outstanding Valhi common stock. U.S. Bank National Association serves as the trustee of the CDCT No. 2. Contran established the CDCT No. 2 as an irrevocable "rabbi trust" to assist Contran in meeting certain deferred compensation obligations that it owes to Harold C. Simmons. If the CDCT No. 2 assets are insufficient to satisfy such obligations, Contran is obligated to satisfy the balance of such obligations as they come due. Pursuant to the terms of the CDCT No. 2, Contran (i) retains the power to vote the shares of Valhi common stock held directly by the CDCT No. 2, (ii) retains dispositive power over such shares and (iii) may be deemed the indirect beneficial owner of such shares.

The CMRT directly holds 0.1% of the outstanding shares of Valhi common stock. Valhi established the CMRT as a trust to permit the collective investment by master trusts that maintain the assets of certain employee benefit plans Valhi and related companies adopt. Mr. Simmons is the sole trustee of the CMRT and a member of the trust investment committee for the CMRT. Mr. Simmons is a participant in one or more of the employee benefit plans that invest through the CMRT.

Mr. Harold C. Simmons is chairman of the board of Valhi, VGI, National, NOA, Dixie Holding, Dixie Rice, Southwest and Contran.

By virtue of the offices held, the stock ownership and his services as trustee, all as described above, (a) Mr. Simmons may be deemed to control certain of such entities and (b) Mr. Simmons and certain of such entities may be deemed to possess indirect beneficial ownership of, and a pecuniary interest in, shares of common stock directly held by certain of such other entities. However, Mr. Simmons disclaims such beneficial ownership of, and such pecuniary interest in, such shares beneficially owned, directly or indirectly, by any of such entities.

The reporting person understands that Valmont Insurance Company ("Valmont"), NL Industries, Inc. ("NL") and a subsidiary of NL directly own 1,000,000, 3,522,967 shares and 1,186,200 shares, respectively, of Valhi common stock as of the date of this statement. Valhi and Tremont LLC are the direct holders of approximately 63.2% and 21.4%, respectively, of the outstanding common stock of NL. Valhi is the holder of 100% of the outstanding membership interests of Tremont LLC and 100% of the outstanding common stock of Valmont. As a result of Valhi's direct and indirect ownership of Valmont, NL and its subsidiary, the reporting person further understands that, pursuant to Delaware law, Valhi treats the shares of Valhi common stock that Valmont, NL and its subsidiary own as treasury stock for voting purposes. For the purposes of this statement, such shares of Valhi common stock that Valmont, NL and its subsidiary hold directly are not deemed outstanding.

SIGNATURE OF REPORTING PERSON
/S/ Andrew Louis

Andrew Louis, Secretary
For: Contran Corporation
DATE 04/15/03

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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	$ (0.08)	$ (0.62)	$ (0.59)	$ (1.75)

Heat Biologics, Inc. basic and diluted				
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

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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

HEAT BIOLOGICS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial reporting. However, certain information or footnote disclosures normally included in complete financial statements prepared in accordance with U.S. GAAP have been condensed, or omitted, pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). In the opinion of the Company s management, the unaudited consolidated financial statements in this Quarterly Report on Form 10-Q include all normal and recurring adjustments necessary for the fair statement of the results for the interim periods presented. The results for the three 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.

HEAT BIOLOGICS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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.

HEAT BIOLOGICS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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.

HEAT BIOLOGICS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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:

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

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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.

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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

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HEAT BIOLOGICS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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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.

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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.

HEAT BIOLOGICS, INC.

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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.

HEAT BIOLOGICS, INC.

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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)

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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:

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complete the ongoing clinical trials of our lead product candidates;

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maintain, expand and protect our intellectual property portfolio;

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seek to obtain regulatory approvals for our product candidates;

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continue our research and development efforts;

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add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and

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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:

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Stock-based compensation;

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Clinical and regulatory costs; and

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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.

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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 to meet the requirements for use of the FBR Sales Agreement or to complete 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.

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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:

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continue to undertake preclinical development and conduct clinical trials for product candidates;

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seek regulatory approvals for product candidates;

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implement additional internal systems and infrastructure; and

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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.

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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

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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.