

HEAT BIOLOGICS, INC.
Form 10-Q
August 13, 2015

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

OR

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

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

Heat Biologics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

26-2844103

(State or other jurisdiction of

I.R.S. Employer

Incorporation or Organization)

Identification No.)

801 Capitola Drive

Durham, NC

27713

(Address of principal executive offices)

(Zip Code)

(919) 240-7133

(Registrant's telephone number, including area code)

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

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

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

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

(Do not check if smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 10, 2015 there were 8,405,434 shares of Common Stock, \$0.0002 par value per share, outstanding.

HEAT BIOLOGICS, INC.

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FORWARD-LOOKING STATEMENTS

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

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

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

PART I FINANCIAL INFORMATION

ITEM 1.

FINANCIAL STATEMENTS

HEAT BIOLOGICS, INC.

Consolidated Balance Sheets

	June 30, 2015 (unaudited)	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	\$ 11,451,395	\$ 3,714,304
Investments, held to maturity (net)	7,912,866	10,698,982
Prepaid expenses and other current assets	836,088	863,227
Total Current Assets	20,200,349	15,276,513
Property and Equipment, net	494,966	445,534
Other Assets		
Restricted cash	101,141	101,129
Deposits	69,798	19,798
Related party receivable	58,017	48,642
Deferred financing costs, net	28,050	24,554
Total Other Assets	257,006	194,123
Total Assets	\$ 20,952,321	\$ 15,916,170
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 814,322	\$ 1,367,426
Accrued expenses and other payables	1,168,259	805,968
Current portion of long term debt	1,009,218	397,465
Total Current Liabilities	2,991,799	2,570,859
Long Term Liabilities		
Long term debt, net of discount and current portion	3,998,517	2,314,124
Other long term liabilities	12,228	
Total Liabilities	7,002,544	4,884,983

Commitments and Contingencies

Stockholders' Equity

Common stock, \$.0002 par value; 50,000,000 shares authorized, 8,404,456 and 6,492,622 shares issued and outstanding at June 30, 2015 (unaudited) and December 31, 2014, respectively	1,363	982
Accumulated other comprehensive loss	(37,051)	
Additional paid in capital	47,779,698	35,894,823
Accumulated deficit	(32,758,116)	(24,135,447)
Total Stockholders' Equity Less Non-Controlling Interest	14,985,894	11,760,358
Non-Controlling Interest	(1,036,117)	(729,171)
Total Stockholders' Equity	13,949,777	11,031,187
 Total Liabilities and Stockholders' Equity	 \$ 20,952,321	 \$ 15,916,170

See Notes to Consolidated Financial Statements

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

	Three Months Ended, June 30,		Six Months Ended, June 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 587,240	\$ 849,359	\$ 1,090,791	\$ 1,382,987
Clinical and regulatory	3,373,758	1,113,186	5,543,231	1,959,570
General and administrative	893,242	1,014,888	2,202,398	2,029,758
Total operating expenses	4,854,240	2,977,433	8,836,420	5,372,315
Loss from operations	(4,854,240)	(2,977,433)	(8,836,420)	(5,372,315)
Interest income	20,702	6,546	29,828	17,521
Other income (expense)	3,865	12,530	25,482	(26,529)
Interest expense	(73,075)		(148,505)	
Total non-operating (expenses) income	(48,508)	19,076	(93,195)	(9,008)
Net loss	(4,902,748)	(2,958,357)	(8,929,615)	(5,381,323)
Net loss non-controlling interest	(189,277)	(111,442)	(306,946)	(203,810)
Net loss attributable to Heat Biologics, Inc.	\$ (4,713,471)	\$ (2,846,915)	\$ (8,622,669)	\$ (5,177,513)
Net loss per share attributable to Heat Biologics, Inc. basic and diluted	\$ (0.56)	\$ (0.44)	\$ (1.13)	\$ (0.80)
Weighted-average number of common shares used in net loss per share attributable to common stockholders basic and diluted	8,401,159	6,452,986	7,612,393	6,432,857
Other comprehensive loss:				
Net loss	(4,902,748)	(2,958,357)	(8,929,615)	(5,381,323)
Unrealized loss on foreign currency translation	(16,185)		(37,051)	
	(4,918,933)	(2,958,357)	(8,966,666)	(5,381,323)

Total other comprehensive
loss

Comprehensive loss

attributable to

non-controlling interest

Comprehensive loss

	(189,277)	(111,442)	(306,946)	(203,810)			
\$	(4,729,656)	\$	(2,846,915)	\$	(8,659,720)	\$	(5,177,513)

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, 2014	\$ 982	\$ 35,894,823	\$ (24,135,447)	\$	\$ (729,171)	\$ 11,031,187
March 2015 public offering, 1,886,000 shares net of underwriters discounts	377	11,400,493				11,400,870
Cashless exercise of options, 5,834 shares						
Vesting of restricted stock, 20,000 shares	4	(4)				
Stock based compensation		786,847				786,847
Stock issuance costs		(302,461)				(302,461)
Accumulated other comprehensive loss				(37,051)		(37,051)
Net loss			(8,622,669)		(306,946)	(8,929,615)
Balance at June 30, 2015	\$ 1,363	\$ 47,779,698	\$ (32,758,116)	\$ (37,051)	\$ (1,036,117)	\$ 13,949,777

See Notes to Consolidated Financial Statements

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

	Six Months Ended	
	June 30,	
	2015	2014
Cash Flows from Operating Activities		
Net loss	\$ (8,929,615)	\$ (5,381,323)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	53,937	21,068
Amortization of debt issuance costs	50,074	
Amortization of bond premium	59,882	106,762
Re-measurement of fair value of stock warrants liability		20,600
Stock based compensation	786,847	497,772
Increase (decrease) in cash arising from changes in assets and liabilities:		
Related party receivable	(9,375)	(11,446)
Prepaid expenses, and other current assets, and restricted cash	23,202	398,454
Deposits	(50,000)	(10,478)
Accounts payable	(569,974)	68,228
Accrued expenses and other payables	362,523	(182,944)
Other long term liabilities	12,228	
Accrued interest		(25,364)
Net Cash Used by Operating Activities	(8,210,271)	(4,498,671)
Cash Flows from Investing Activities		
Proceeds from maturities of short term investments	12,967,509	9,631,543
Purchases of short term investments	(10,241,275)	(3,305,972)
Purchases of property and equipment	(103,369)	(448,234)
Net Cash Provided by Investing Activities	2,622,865	5,877,337
Cash Flows from Financing Activities		
Proceeds from March 2015 public offering, net of underwriting discounts	11,400,870	
Proceeds from the exercise of stock options		37,719
Proceeds from long term debt	2,242,575	
Stock issuance costs	(302,461)	
Net Cash Provided by Financing Activities	13,340,984	37,719

Effect of exchange rate changes on cash and cash equivalents		(16,487)		
Net Increase in Cash and Cash Equivalents		7,737,091		1,416,385
Cash and Cash Equivalents Beginning of Period		3,714,304		4,566,992
Cash and Cash Equivalents End of Period	\$	11,451,395	\$	5,983,377
Supplemental Disclosure for Cash Flow Information				
Interest paid	\$	98,430	\$	
Cashless exercise of stock warrants	\$		\$	143,190

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Summary of Significant Accounting Policies

Basis of presentation and Principles of Consolidation

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

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

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

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

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company has accumulated a deficit of approximately \$32.8 million as of June 30, 2015 and a net loss of approximately \$8.9 million for the six months ended June 30, 2015, and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. If the Company is unable to obtain the necessary capital, it will need to pursue a plan to scale back its operations, license or sell its assets, seek to be acquired by another entity and/or cease operations.

HEAT BIOLOGICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

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

2. Fair Value of Financial Instruments

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

As a basis for determining the fair value of certain of the Company's financial instruments, the Company utilizes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level I Observable inputs such as quoted prices in active markets for identical assets or liabilities.

Level II Observable inputs, other than Level I prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level III Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the entire fair value measurement requires management to make judgments and consider factors specific to the asset or liability. All of the Company's cash equivalents, which consist of money market funds, are classified within Level I of the fair value hierarchy because they are valued using quoted market prices.

HEAT BIOLOGICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

3. Investments

Investments in certain securities may be classified into three categories:

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

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

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

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

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

	Amortized Cost		Gross Unrealized (Losses)		Estimated Fair Value
December 31, 2014					
Certificates of deposit, corporate notes and bonds	\$ 10,698,982	\$	(2,209)	\$	10,696,773
June 30, 2015					
Certificates of deposit, tri-party repurchase agreement, corporate notes and bonds	\$ 7,912,866	\$	(5,883)	\$	7,906,983

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

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

		Less than 1 Year		Total
Certificates of deposit, tri-party repurchase agreement, corporate notes and bonds	\$	7,912,866	\$	7,912,866

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

(Unaudited)

4. Property and Equipment

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

Property and equipment consisted of the following:

	June 30,		December 31,
	2015		2014
Furniture and fixtures	\$ 53,342	\$	50,391
Computers	33,017		24,174
Lab equipment	538,998		447,423
Total	625,357		521,988
Accumulated depreciation	(130,391)		(76,454)
Property and equipment, net	\$ 494,966	\$	445,534

Depreciation expense was \$28,325 and \$18,898 for the three months ended June 30, 2015 and 2014, respectively. Depreciation expense was \$53,937 and \$21,068 for the six months ended June 30, 2015 and 2014, respectively.

5. Accrued Expenses and other payables

Accrued expenses consist of the following:

	June 30,		December 31,
	2015		2014
Compensation and related benefits	\$ 218,299	\$	519,092

Patent fees	30,000	40,000
Deferred rent	56,300	51,155
Accrued professional services fees	203,406	
Accrued clinical trial expense	660,254	195,721
	\$ 1,168,259	\$ 805,968

6. Debt Issuance Costs

During 2014, the Company recorded \$323,021 to debt discount for the initial fair value of the warrant to purchase common stock and \$27,500 to deferred financing costs related to third party fees paid in connection to the Square 1 Bank loan, which are amortized straight-line over the 42 months term of the loan which approximates the effective interest method. In June 2015, deferred financing costs increased \$7,425 for the Tranche 3 loan related fees.

Total amortization expense for the debt issuance costs was \$50,074 and \$0 during the six months ended June, 2015 and 2014, respectively.

HEAT BIOLOGICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

7. Notes Payable

Square 1 Bank Loan

In August 2014, the Company entered into a secured loan with Square 1 Bank (Loan). The Loan provides the Company with a term loan in the aggregate principal amount not to exceed \$7,500,000 to be used to supplement working capital. On June 22, 2015 the Company and Square 1 Bank entered into the First Amendment which amended the terms for Tranche 3 and Tranche 4 as follows: (i) the Tranche 3 Funding Condition means Bank's receipt on or before June 30, 2015 of evidence satisfactory to the Bank of the initiation of the Company's Phase 1B trial for lung cancer indication; (ii) the Tranche 4 Availability End Date is December 31, 2015; and (iii) the Tranche 4 Funding Condition means Bank's receipt on or before December 31, 2015 of evidence satisfactory to the Bank of full enrollment of Company's Phase 1/2 clinical trial for HS-410. The Loan is available to the Company in four tranches: \$1,500,000 was made available to the Company on August 22, 2014 (Tranche 1 Loan), \$1,500,000 was made available to the Company upon its enrollment of its first patient in its the Phase 2 clinical trial for HS-110 (Tranche 2 Loan), \$2,250,000 was made available to the Company upon the initiation of the Phase 1B trial for lung cancer indication on June 30, 2015 (Tranche 3 Loan) and \$2,250,000 will be available to the Company upon Square 1 Bank's receipt on or before December 31, 2015 of evidence satisfactory to it of the full enrollment of our Phase 1/2 clinical trial for HS -410 (Tranche 4 Loan). As of June 30, 2015, the Company had drawn down \$1,500,000 under each of the Tranche 1 Loan and Tranche 2 Loan, and \$2,250,000 under the Tranche 3 Loan for a total of \$5,250,000.

The Loan accrues interest monthly at an interest rate of 3.05% plus prime or 6.30 % per annum whichever is greater. The Tranche 1 Loan is payable as interest-only until June 30, 2015 and thereafter interest is payable in monthly installments of principal plus accrued interest until February 22, 2018. The Tranche 2 Loan is payable as interest-only prior to October 31, 2015 and thereafter is payable in monthly installments of principal plus accrued interest until February 22, 2018. The Tranche 3 Loan is payable as interest-only prior to October 31, 2015 and thereafter is payable in monthly installments of principal plus accrued interest until February 22, 2018. The Tranche 4 Loan is available until December 31, 2015 and is payable in monthly installments of principal plus accrued interest until February 22, 2018. The Company has made \$0 in principal payments and \$98,430 and \$24,150 in interest payments on the outstanding loan for the periods ended June 30, 2015 and December 31, 2014. The agreement with Square 1 Bank sets forth various affirmative and negative covenants. The failure of the Company to comply with the covenants constitutes a default under the Loan. The covenants include the Company having at least two ongoing clinical trials at all times, the attainment of the funding conditions set forth in the agreement and covenants regarding financial reporting, limits on the Company's cash burn, incurrence of indebtedness, permitted investments, encumbrances, distributions, investments and mergers and acquisitions. The Loan is also secured by a security interest in all of the Company's personal property, excluding its intellectual property. The Company is in compliance with the covenants of

the Loan as of June 30, 2015.

8. Stock-Based Compensation

Restricted Stock

During the three and six month period ended June 30, 2015, the Company recognized \$23,700 and \$90,000 in stock-based compensation expense related to the issuance of restricted stock to non-employees in exchange for services. There was no stock-based compensation expense for restricted stock for non-employees during the three and six month periods ended June 30, 2014.

Common Stock Warrants

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

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

(Unaudited)

Stock Options

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

	Shares		Weighted Average Exercise Price
Outstanding, December 31, 2014	1,018,590	\$	5.04
Granted	205,000	\$	6.23
Exercised	(6,522)	\$	0.48
Forfeited	(173,048)	\$	6.57
Outstanding, June 30, 2015	1,044,020	\$	5.05

The weighted average grant-date fair value of stock options granted during the six months ended June 30, 2015 was \$4.03. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions for stock options granted during the six months ended June 30, 2015:

Dividend yield	0.0%
Expected volatility	86.4%
Risk-free interest rate	1.66%
Expected lives (years)	6.1

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

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

The Company recognized \$324,396 and \$328,660 in stock-based compensation expense for the three months ended June 30, 2015 and 2014, respectively and \$696,847 and \$497,772 for the six months ended June 30, 2015 and 2014, respectively for the Company's stock option awards.

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

	Options Outstanding			Options Vested and Exercisable		
	Weighted			Weighted		
	Average			Average		
	Remaining	Weighted		Remaining	Weighted	
Balance	Contractual	Average	Balance	Contractual	Average	
as of	Life	Exercise	as of	Life	Exercise	
6/30/2015	(Years)	Price	6/30/2015	(Years)	Price	
1,044,020	7.5	\$5.05	615,063	6.3	\$3.71	

As of June 30, 2015, the unrecognized stock-based compensation expense related to unvested stock options was \$2,988,921 which is expected to be recognized over a weighted average period of approximately 16.1 months.

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

(Unaudited)

9. Financing*Public Offering*

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

10. Net Loss Per Share

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Net loss	\$ (4,902,748)	\$ (2,958,357)	\$ (8,929,615)	\$ (5,381,323)
Net loss:)
Non-controlling interest	(189,277)	(111,442)	(306,946)	(203,810)
	\$ (4,713,471)	\$ (2,846,915)	\$ (8,622,669)	\$ (5,177,513)

Net loss attributable to Heat Biologics, Inc.

Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc. basic and diluted

	8,401,159	6,452,986	7,612,393	6,432,857
Net loss per share attributable to Heat Biologics, Inc. basic and diluted	\$ (0.56)	\$ (0.44)	\$ (1.13)	\$ (0.80)

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

For the Six Months Ended

June 30,

	2015	2014
Outstanding stock options	1,044,020	599,486
Common stock warrants	17,392	17,392
Underwriters warrants	125,000	125,000

HEAT BIOLOGICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

11. Income Tax

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statements 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 June 30, 2015 and December 31, 2014, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of operations and comprehensive loss. As of June 30, 2015 and December 31, 2014, the Company had no such accruals.

ITEM 2.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this quarterly report. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed below and elsewhere in this quarterly report. This discussion should be read in conjunction with the accompanying unaudited condensed consolidated financial statements and the audited condensed consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission on March 27, 2015 (the 2014 Annual Report). This discussion may contain forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements.

OVERVIEW

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

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

Currently, two of our product candidates, HS-110 and HS-410 are being evaluated in Phase 2 clinical trials for non-small cell lung cancer and bladder cancer, respectively.

HS-110

We continue a Phase 2 clinical trial of our therapeutic vaccine candidate HS-110 (Viagenpumatucel-L) in non-small cell lung cancer (NSCLC) patients. HS-110 is a biologic product comprising a lung cancer cell line that has been genetically modified using our *ImPACT* technology platform to secrete a wide range of lung cancer associated antigens bound to gp96 proteins and activate a T-cell mediated pan-antigen immune response against the patient's cancer. The Phase 2 clinical trial will evaluate HS-110 in combination with low dose cyclophosphamide versus chemotherapy alone in third-line or fourth-line NSCLC patients. The trial is expected to enroll 123 patients at approximately 20 to 30 investigative centers and enrollment is anticipated to be completed during the fourth quarter of 2015.

A second multi-arm trial was initiated in the second quarter of 2015 to look at various other combinations of agents with HS-110. The first combination partners to be evaluated with HS-110 include continuous oxygen, A2A-receptor antagonist, and both oxygen and A2AR antagonist combined. Each cohort consists of 9 patients, and new cohorts will be added based on emerging preclinical data.

HS-410

We completed enrollment in the Phase 1 portion of a Phase 1/2 bladder cancer trial with our therapeutic vaccine candidate HS-410 (Vesigenurtacel-L) in October 2014, and initiated the Phase 2 portion. HS-410 is a biologic product comprising a bladder cancer cell line genetically modified to secrete a wide range of bladder cancer antigens bound to gp96 molecules and thereby activate a T-cell mediated pan-antigen immune response against the patient's bladder cancer. The Phase 2 trial will examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, non-muscle-invasive bladder cancer who have completed surgical resection. The Phase 2 study is evaluating HS-410 in combination with intravesical bacillus Calmette-Guérin (BCG) immunotherapy instillations as well as monotherapy. We anticipate including up to 20 clinical sites, 100 patients, and expect to complete enrollment in the study in the fourth quarter of 2015.

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

On February 26, 2015 we announced we had formed a partnership with the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC) to accelerate Phase 2 enrollment in NMIBC and to initiate planning for the Phase 3 trial.

On March 5, 2015, we were notified that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for HS-410 for the treatment of non-muscle invasive bladder cancer. We believe that this designation will expedite our development of HS-410.

ComPACT

On June 15, 2015, we announced the development of a second platform incorporating various T cell costimulatory ligand fusion proteins into the gp96-Ig expression vector. In the first version of this platform, OX40L-Fc is engineered to be co-expressed with gp96-Ig, and was demonstrated to provide superior costimulation of antigen-specific CD8+ T cells in pre-clinical models as compared to OX40 agonistic monoclonal antibodies. The human version of this platform has been generated, and we anticipate filing our first IND using this platform in the second half of 2016.

We commenced active operations in June 2008. Our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates and undertaking preclinical and clinical studies of our most advanced product candidates. To date, we have not generated any revenues and have financed our operations with net proceeds from the private placement of our preferred stock, our initial public offering in which we received gross proceeds of \$27.0 million and net proceeds of \$24.3 million, our recent public offering that was completed on March 16, 2015 of 1,886,000 shares of our common stock at a closing price of \$6.50 per share for gross proceeds of \$12.3 million and net proceeds to us of \$11.1 million, and our debt commitments. As of June 30, 2015, we had an accumulated deficit of (\$32,758,116). We had net losses of (\$8,929,615) and (\$5,381,323) for the six months ended June 30, 2015 and 2014, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and initiate and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Accordingly, there is substantial doubt that we can continue as an on-going business for the next twelve months unless we obtain additional capital. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We will need to generate significant revenues to achieve profitability, and we may never do so.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as "critical" because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates which also would have been reasonable could have been used, which would have resulted in different financial results.

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates based on historical experience and make various assumptions, which management believes to be reasonable under the circumstances, which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

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

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Stock-based compensation,

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Clinical and regulatory costs, and

.

Research and development costs

RESULTS OF OPERATIONS

Comparison of the Three Months ended June 30, 2015 and 2014

Research and development expense. Research and development expense for the three months ended June 30, 2015 (2015 Quarter) was \$587,240 compared to \$849,359 for the three months ended June 30, 2014 (2014 Quarter). The \$262,119 decrease from the 2014 Quarter to the 2015 Quarter is attributable to a decrease of \$320,917 in pre-manufacturing costs associated with preparing to produce vaccines for use in our clinical trials, as well as decreases in patent, license and other professional fees of \$52,412. These decreases are offset by increases of \$62,903 in compensation costs associated with new hires, \$39,160 in lab supplies and \$9,147 in depreciation related to the build out of the lab facility and other associated costs.

Clinical and regulatory expense. Clinical and regulatory expense for the 2015 Quarter was \$3,373,758 compared to \$1,113,186 for the 2014 Quarter. The \$2,260,572 increase from the 2014 Quarter to the 2015 Quarter is attributable to increases in clinical trial execution costs of \$703,156, increases in investigator payments of \$552,971, as well as an increase of \$540,178 in costs related to the production of vaccines for our clinical trials. Additionally, personnel costs, including consultants, increased by \$215,218. Professional fees increased by \$144,179, facilities increased by \$58,383, and travel increased by \$15,592. Taxes associated with clinical trial execution in Australia were \$30,895 in the 2015 Quarter but were zero in the 2014 Quarter.

General and administrative expense. General and administrative expense for the 2015 Quarter was \$893,242 compared to \$1,014,888 for the 2014 Quarter. The \$121,646 decrease from the 2014 Quarter to the 2015 Quarter is attributable to a decrease of \$72,970 in personnel expense including consultants, decrease of \$32,567 in facility expense due to allocation to other departments, a decrease of \$14,639 in travel expense offset by an increase of \$36,205 related to professional services such as accountants, attorneys and investor relations. Franchise taxes were paid in Quarter 1 of 2015 and Quarter 2 of 2014 resulting in a decrease of \$37,675 in the 2015 Quarter.

Interest income. Interest income was \$20,702 for the 2015 Quarter as compared to \$6,546 for the 2014 Quarter. The increase of \$14,156 is de minimis.

Interest expense. Interest expense was \$73,075 for the 2015 Quarter compared to \$0 for the 2014 Quarter due to the Square 1 Bank loans, the first of which, the Tranche 1 Loan, was entered into in August 2014. There were no loans during the 2014 Quarter.

Comparison of the Six Months ended June 30, 2015 and 2014

Research and development expense. Research and development expense for the six months ended June 30, 2015 (2015 Period) was \$1,090,791 compared to \$1,382,987 for the six months ended June 30, 2014 (2014 Period). The \$292,196 decrease from the 2014 Period to the 2015 Period is attributable to a decrease of \$559,290 in pre-manufacturing costs associated with preparing to produce vaccines for use in our clinical trials, as well as decreases in patent, license and other professional fees of \$80,359. These decreases are offset by increases of \$157,556 in compensation costs associated with new hires, \$142,619 in lab supplies and other costs, and \$47,278 in depreciation related to the build out of the lab facility and other associated costs.

Clinical and regulatory expense. Clinical and regulatory expense for the 2015 Period was \$5,543,231 compared to \$1,959,570 for the 2014 Period. The \$3,583,661 increase from the 2014 Period to the 2015 Period is attributable to increases in clinical trial execution costs of \$1,202,531, increased investigator payments of \$840,714, as well as an

increase of \$597,156 in costs related to the production of vaccines for our clinical trials. Additionally, personnel cost, including consultants, increased by \$466,979. Professional fees increased by \$210,019, facilities costs increased by \$147,855, travel increased by \$34,921, and license fees increased by \$25,000. Taxes associated with clinical trial execution in Australia were \$58,486 in the 2015 Period but were zero in the 2014 Period.

General and administrative expense. General and administrative expense for the 2015 Period was \$2,202,398 compared to \$2,029,758 for the 2014 Period. The \$172,640 increase from the 2014 Period to the 2015 Period is attributable to \$136,164 primarily related to increase in pay to certain key employees, \$85,437 related to an increase in professional services such as accountants, attorneys and investor relations and \$18,140 increase in travel. These increases are offset by a decrease in facility and related costs of \$55,379 as well as a decrease of \$11,722 in depreciation.

Interest income. Interest income was \$29,828 for the 2015 Period as compared to \$17,521 for the 2014 Period. The increase of \$12,307 is de minimis.

Interest expense. Interest expense was \$148,505 for the 2015 Period compared to \$0 for the 2014 Period due to the Square 1 Bank loans, the first of which, the Tranche 1 Loan, was entered into in August 2014. There were no loans during the 2014 Period.

Balance Sheet at June 30, 2015 and December 31, 2014

Prepaid expenses and other current assets. Prepaid expenses and other current assets were \$836,088 as of June 30, 2015 compared to \$863,227 as of December 31, 2014. The decrease of \$27,139 was primarily due to the decrease in the amount paid in advance for our clinical research organizations (CRO) as we progress with our Phase 2 clinical trial studies for HS-110 and HS-410.

Accounts Payable. Accounts payable was \$814,322 as of June 30, 2015 compared to \$1,367,426 as of December 31, 2014. The decrease of \$553,104 was primarily related to a payable that was due to one of our drug manufacturers at December 31, 2014, which was subsequently paid in the first quarter of 2015.

Accrued Expenses. Accrued expenses were \$1,168,259 as of June 30, 2015 compared to \$805,968 as of December 31, 2014. The increase of \$362,291 was primarily related to the increase of subjects enrolled for our clinical trials.

Long Term Debt Including Current Portion. The current portion of long term debt was \$1,009,218 as of June 30, 2015 compared to \$397,465 as of December 31, 2014. In 2014 the Company only had outstanding debt from Tranche 1 of the Square 1 loan from the end of August and Tranche 2 from the end of November. As of June 30, 2015 the Company had drawn down \$1,500,000 under each of the Tranche 1 and Tranche 2 Loan, and 2,250,000 under Tranche 3 Loan for a total of \$5,250,000.

Foreign currency translation. The foreign currency translation adjustment included in other comprehensive income was \$37,051 for the 2015 Period and \$0 for the 2014 Period.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

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

will need to pursue a plan to scale back our operations, license or sell our assets, seek to be acquired by another entity and/or cease operations. As of June 30, 2015, we had \$19,364,261 in cash and cash equivalents and short term investments.

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

Cash flows

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

Investing activities. Cash provided by investing activities for the 2015 Period was primarily from proceeds from maturities and purchase of various short-term investments as well as for the purchase of property and equipment. Cash provided by investing activity in the 2014 Period was from proceeds from maturities of short-term investments offset by purchase of property and equipment.

Financing activities. Cash provided by financing activities during the 2015 Period was primarily from the March 2015 public offering and exercise of the over-allotment option which generated net proceeds of approximately \$11.1 million (after deduction of offering expenses) as well as \$2,242,575 in proceeds from Tranche 3 of the Loan.

Funding requirements

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

OFF-BALANCE SHEET ARRANGEMENTS

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

ITEM 3.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable to smaller reporting companies.

ITEM 4.

CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2015. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended (the Exchange Act) is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure

controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such a date, our disclosure controls and procedures were effective at the reasonable assurance level.

PART II OTHER INFORMATION

ITEM 1.

LEGAL PROCEEDINGS.

None.

ITEM 1A.

RISK FACTORS.

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

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

We currently have no products for sale and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA, and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, marketing, adverse event reporting and recordkeeping of our product candidates. Until, and unless, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot commercialize our product candidates and will not have product revenues. For the foreseeable future, we will have to fund all of our operations from equity and debt offerings, cash on hand, grants, our Square 1 Bank debt facility. We believe that due to our current cash position and estimates of expenses, there is sufficient doubt about our ability to continue as a going concern. In addition, changes may occur that would consume our available capital at a faster pace than expected, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation. Moreover, pre-clinical studies and clinical trials may not start or be completed as we forecast and may not achieve the desired results. Therefore, we expect that we will seek additional sources of funding, such as additional financing or grant funding, and additional financing may not be available on favorable terms, if at all. 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 period of June 30, 2015 and the year ended December 31, 2014, we incurred a net loss of (\$8,929,615) and (\$12,243,211), respectively. We have an accumulated deficit of (\$32,758,116) through June 30, 2015. We expect to continue to incur operating losses until such time, if ever, as we are able to achieve sufficient levels of revenue from operations. Our ability to achieve profitability will depend on the market acceptance of our product offerings and our capacity to develop, introduce and sell our products to our targeted markets. There can be no assurance that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

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

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

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

ITEM 2.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

RECENT SALES OF UNREGISTERED SECURITIES

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

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

- Neither we nor any person acting on our behalf solicited any offer to buy nor sell securities by any form of general solicitation or advertising.
- At the time of the purchase, the firm was an accredited investor, as defined in Rule 501(a) of the Securities Act.
- The firm has had access to information regarding our company and is knowledgeable about us and our business affairs.
- Shares of common stock issued to the firm were issued with a restrictive legend and may only be disposed of pursuant to an effective registration or exemption from registration in compliance with federal and state securities laws.

USE OF PROCEEDS

In connection with our initial public offering, we sold 2,700,000 (including the 200,000 over-allotment option shares) shares of our common stock at a price of \$10.00 per share. Aggregate gross proceeds from the IPO, were \$27.0 million and net proceeds received after underwriting commissions and offering expenses of \$2.7 million were \$24.3 million.

As of June 30, 2015, we have used approximately \$22.9 million of the net proceeds, in connection with our clinical trials, manufacturing and general and administrative expenses. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in the prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act other than as previously reported.

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.

EXHIBIT INDEX

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

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Filed herewith.