AmpliPhi Biosciences Corp
Form 10-Q
November 10, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 001-37544

AMPLIPHI BIOSCIENCES CORPORATION
(Exact name of registrant as specified in its charter)

Washington	**91-1549568**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

3579 Valley Centre Drive, Suite 100

San Diego, California
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: **(858) 829-0829**

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 x 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 x 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 as defined in Rule 12b-2 of the Exchange Act. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a small reporting company) Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ¨ No x

The number of shares of the Registrant's Common Stock, par value $0.01 per share, outstanding at November 10, 2016 was 11,120,394.

TABLE OF CONTENTS

AmpliPhi Biosciences Corporation

Consolidated Balance Sheets

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$3,967,000	$9,370,000
Accounts receivable	24,000	125,000
Prepaid expenses and other current assets	570,000	521,000
Total current assets	4,561,000	10,016,000
Property and equipment, net	1,152,000	1,131,000
In process research and development	12,446,000	12,446,000
Acquired patents, net	315,000	338,000
Goodwill	7,562,000	7,562,000
Total assets	$26,036,000	$31,493,000
Liabilities, Series B redeemable convertible preferred stock and stockholders' equity		
Current liabilities		
Accounts payable, accrued expenses and other	$2,173,000	$1,464,000
Deferred revenue	18,000	245,000
Accrued severance	10,000	308,000
Dividends payable	953,000	368,000
Total current liabilities	3,154,000	2,385,000
Derivative liabilities	1,649,000	1,499,000
Deferred tax liability	3,005,000	3,005,000
Total liabilities	7,808,000	6,889,000
Series B redeemable convertible preferred stock $0.01 par value, 9,357,935 shares authorized at September 30, 2016 and December 31, 2015, no shares and 7,527,853 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively (liquidation preference of $0 and $13,383,000 at September 30, 2016 and December 31, 2015, respectively)	-	11,890,000
Stockholders' equity		
Common stock, $0.01 par value, 670,000,000 shares authorized at September 30, 2016 and December 31, 2015, 11,120,394 and 5,883,503 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	111,000	59,000
Additional paid-in capital	389,977,000	375,177,000
Accumulated deficit	(371,860,000)	(362,522,000)
Total stockholders' equity	18,228,000	12,714,000
Total liabilities, Series B redeemable convertible preferred stock and stockholders' equity	$26,036,000	$31,493,000

See accompanying condensed notes to consolidated financial statements.

AmpliPhi Biosciences Corporation

Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016 (Unaudited)	2015 (Unaudited)	2016 (Unaudited)	2015 (Unaudited)
Revenue	$29,000	$143,000	$238,000	$347,000
Operating expenses				
Research and development	1,655,000	728,000	4,876,000	2,777,000
General and administrative	1,781,000	1,843,000	6,876,000	4,857,000
Total operating expenses	3,436,000	2,571,000	11,752,000	7,634,000
Loss from operations	(3,407,000)	(2,428,000)	(11,514,000)	(7,287,000)
Other income (expense)				
Change in fair value of derivative liabilities	1,032,000	7,738,000	2,403,000	9,304,000
Other income (expense)	-	129,000	(227,000)	(302,000)
Total other income	1,032,000	7,867,000	2,176,000	9,002,000
Net (loss) income	(2,375,000)	5,439,000	(9,338,000)	1,715,000
Excess of fair value of consideration transferred on conversion of Series B redeemable convertible preferred stock	(1,214,000)	-	(3,580,000)	-
Accretion of Series B redeemable convertible preferred stock	-	(7,163,000)	(1,858,000)	(9,329,000)
Net loss attributable to common stockholders	$(3,589,000)	$(1,724,000)	$(14,776,000)	$(7,614,000)
Per share information:				
Net loss per share of common stock - basic	$(0.32)	$(0.30)	$(1.72)	$(1.45)
Weighted average number of shares of common stock outstanding - basic	11,120,394	5,813,063	8,590,772	5,247,508
Net loss per share of common stock - diluted	$(0.32)	$(0.30)	$(1.77)	$(1.45)
Weighted average number of shares of common stock outstanding - diluted	11,120,394	5,813,063	8,648,914	5,247,508

See accompanying condensed notes to consolidated financial statements.

AmpliPhi Biosciences Corporation

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity

	Redeemable Convertible Preferred Stock Series B		Stockholders' Equity Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balances, December 31, 2014	8,671,040	$1,990,000	3,983,182	$40,000	$365,403,000	$(362,006,000)	$3,437,000
Net loss	-	-	-	-	-	(516,000)	(516,000)
Accretion of dividends on Series B redeemable convertible preferred stock	-	1,307,000	-	-	(1,307,000)	-	(1,307,000)
Accretion to redemption value of Series B redeemable convertible stock	-	8,971,000	-	-	(8,971,000)	-	(8,971,000)
Conversion of Series B redeemable convertible preferred stock to common stock	(1,143,187)	(378,000)	228,637	2,000	1,504,000	-	1,506,000
Common stock issued in March 2015 financing, net of offering costs	-	-	1,575,758	16,000	8,250,000	-	8,266,000
Warrants exercised	-	-	56,645	1,000	1,072,000	-	1,073,000
Warrants reclassified from liabilities to equity due	-	-	-	-	5,462,000	-	5,462,000

to amendment of warrants							
Warrants reclassified from liabilities to equity due to increase in authorized shares	-	-	-	-	3,281,000	-	3,281,000
Exercise of common stock options and other	-	-	39,281	-	-	-	-
Stock-based compensation	-	-	-	-	479,000	-	479,000
Stock-based compensation - severance	-	-	-	-	4,000	-	4,000
Balances, December 31, 2015	7,527,853	11,890,000	5,883,503	59,000	375,177,000	(362,522,000)	12,714,000
Net loss	-	-	-	-	-	(9,338,000)	(9,338,000)
Accretion of dividends on Series B redeemable convertible preferred stock	-	365,000	-	-	(365,000)	-	(365,000)
Accretion to redemption value of Series B redeemable convertible stock	-	1,493,000	-	-	(1,493,000)	-	(1,493,000)
Conversion of Series B redeemable convertible preferred stock to common stock	(7,527,853)	(13,748,000)	2,359,025	24,000	10,605,000	-	10,629,000
Warrants issued for Novolytics assets	-	-	-	-	204,000	-	204,000
Common stock issued in June 2016 financing, net of offering costs and	-	-	2,127,660	21,000	2,613,000	-	2,634,000

warrants							
Common stock issued pursuant to anti-dilution rights	-	-	750,206	7,000	1,538,000	-	1,545,000
Stock-based compensation	-	-	-	-	1,698,000	-	1,698,000
Balances, September 30, 2016 (Unaudited)	-	$-	11,120,394	$111,000	$389,977,000	$(371,860,000)	$18,228,000

See accompanying condensed notes to consolidated financial statements.

AmpliPhi Biosciences Corporation

Consolidated Statement of Cash Flows

	Nine Months Ended September 30,	
	2016 (Unaudited)	2015 (Unaudited)
Operating activities:		
Net (loss) income	$(9,338,000)	$1,715,000
Adjustments required to reconcile net (loss) income to net cash used in operating activities:		
Change in fair value of derivative and warrant liabilities	(2,403,000)	(9,304,000)
Warrants and other allocable expenses	431,000	213,000
Gain on re-valuation of liquidated damages liability	-	(120,000)
Amortization of patents	23,000	23,000
Depreciation	245,000	217,000
Stock-based compensation	1,698,000	253,000
Changes in operating assets and liabilities:		
Accounts receivable	101,000	60,000
Accounts payable, accrued expenses, deferred revenue and other	482,000	(11,000)
Accrued severance	(298,000)	(64,000)
Prepaid expenses and other current assets	(49,000)	(446,000)
Net cash used in operating activities	(9,108,000)	(7,464,000)
Investing activities:		
Purchases of property and equipment	(266,000)	(160,000)
Net cash used in investing activities	(266,000)	(160,000)
Financing activities:		
Proceeds from warrant exercises	-	396,000
Costs of Series B redeemable convertible preferred stock conversion to common stock	(173,000)	-
Dividend payments	(80,000)	-
Proceeds from issuance of common stock, net	4,224,000	12,384,000
Net cash provided by financing activities	3,971,000	12,780,000
Net (decrease) increase in cash and cash equivalents	(5,403,000)	5,156,000
Cash and cash equivalents, beginning of period	9,370,000	6,581,000
Cash and cash equivalents, end of period	$3,967,000	$11,737,000
Supplemental schedule of non-cash financing activities:		
Accretion of Series B redeemable convertible preferred stock	$1,858,000	$9,329,000
Fair value of warrant liability upon issuance	$1,816,000	$4,210,000

See accompanying condensed notes to consolidated financial statements.

6

AmpliPhi Biosciences Corporation

Condensed Notes to Consolidated Financial Statements

September 30, 2016
(Unaudited)

1. Organization and Description of the Business

AmpliPhi Biosciences Corporation (the "Company") was incorporated in the state of Washington in 1989 under the name Targeted Genetics Corporation. In February 2011, Targeted Genetics Corporation changed its name to AmpliPhi Biosciences Corporation. The Company is dedicated to developing novel antibacterial therapies called bacteriophage (phage). Phages are naturally occurring viruses that preferentially target and kill their bacterial targets.

2. Liquidity

The Company has prepared these consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, the Company has incurred net losses since its inception, has negative operating cash flows and has an accumulated deficit of $371.9 million as of September 30, 2016, $56.4 million of which has been accumulated since January of 2011, when the Company began its focus on bacteriophage development. As of September 30, 2016, the Company had cash and cash equivalents of $4.0 million. Management believes that the Company's existing resources will be sufficient to fund the Company's planned operations through the end of 2016. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

The Company's ability to raise additional funds will depend, in part, on the success of the Company's preclinical studies and clinical trials and other product development activities, regulatory events, the Company's ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect the value or prospects of the Company, as well as factors related to financial, economic, and market conditions, many of which are beyond the Company's control. The Company cannot be certain that sufficient funds will be available to it when required or on acceptable terms, if at all. If adequate funds are not available on a timely basis or on acceptable terms, the Company may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of its development programs or other operations, dispose of technology or assets, pursue an acquisition of the Company by a third party at a price that may result in a loss on investment for its stockholders, enter

into arrangements that may require the Company to relinquish rights to certain of its product candidates technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on the Company's business, financial condition and results of operations and result in a loss of investment by its stockholders.

3. Significant Accounting Policies

The Company's significant accounting policies are described in Note 3 to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission (SEC). Since the date of those financial statements, there have been no material changes to the Company's significant accounting policies. The interim consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries Biocontrol Limited, Ampliphi d.o.o., and AmpliPhi Australia Pty Ltd. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2015 included in the Company's Annual Report on Form 10-K, filed with the SEC. The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) for interim financial statements and in accordance with the instructions to Form 10-Q. Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

In the opinion of management, the accompanying financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2016 and the results of its operations for the three and nine months ended September 30, 2016 and 2015. Interim results are not necessarily indicative of results for the full year or any future period.

Reverse Stock Split

On August 3, 2015, the Company filed Articles of Amendment to Amended and Restated Articles of Incorporation with the Secretary of State of the State of Washington that effected a 1-for-50 (1:50) reverse stock split of its common stock, par value $0.01 per share, effective August 7, 2015. On August 3, 2015, the Company increased its authorized common stock, from 445,000,000 to 670,000,000 shares. The par value of its common stock was unchanged at $0.01 per share, post-split. All warrant, stock option, and per share information in the consolidated financial statements

gives retroactive effect to the 1-for-50 reverse stock split that was effected on August 7, 2015.

Use of Estimates

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these financial statements, management used significant estimates in the following areas, among others: the determination of the fair value of stock-based awards, the fair value of liability-classified derivatives, the fair value of liability-classified warrants, the valuation of long-lived assets, including in-process research and development, patents and goodwill, accrued expenses and the recoverability of the Company's net deferred tax assets and related valuation allowance.

Revision of Immaterial Error

During the Company’s financial statement preparation and review process for the three months ended September 30, 2016, an error was identified in the assumptions used to calculate the fair value of the dilutive financing derivative issued in connection with the Common Stock Issuance Agreement (CSIA). The dilutive financing derivative liability fair value was calculated using the Monte Carlo model, which included various key assumptions and estimates. The error resulted in an overstatement of net loss of $1.1 million and an understatement of net loss attributable to common stockholders of $0.1 million for the three and six months ended June 30, 2016. The error also resulted in an understatement of total liabilities and an overstatement of stockholder’s equity in the amount of $0.1 million. Based on a qualitative and quantitative analysis of the error, the Company concluded that the error is immaterial to the interim consolidated financial statements for the three and six months ended June 30, 2016 and had no effect on the trend of financial results. The correction of the foregoing error is reflected in the consolidated financial statements for the three and nine months ended September 30, 2016.

Warrant and Preferred Shares Conversion Feature Liability

The Company accounts for both warrants with anti-dilution adjustment provisions and other features and preferred share features with anti-dilution adjustment provisions under the applicable accounting guidance which requires the warrant and the preferred share features to be recorded as liabilities and adjusted to fair value at each reporting period.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The ASU creates a single source of revenue guidance for companies in all industries. The new standard provides guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers, unless the contracts are within the scope of other accounting standards. It also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets. This guidance, as amended, must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach and will be effective for fiscal years beginning after December 15, 2017. The Company has not yet evaluated the potential impact of adopting the guidance on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 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*, which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In February 2015, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which amends the FASB Accounting Standards Codification and creates Topic 842, "Leases." The new topic supersedes Topic 840, "Leases," and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018. ASU 2016-02 mandates a modified retrospective transition method. The Company has not yet evaluated the potential impact of adopting the guidance on its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*. The ASU is part of a simplification initiative aimed at reducing complexity in accounting standards. Current GAAP requires the deferred taxes for each jurisdiction (or tax-paying component of a jurisdiction) to be presented as a net current asset or liability and net noncurrent asset or liability. To simplify presentation, the new guidance requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The standard is effective for public entities for annual reporting periods beginning after December 15, 2016, and interim periods therein. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification (“ASC”) Topic 718, Compensation – Stock Compensation. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. The Company has not yet evaluated the potential impact of adopting the guidance on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Cash Flow Statements, Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow classification issues with the objective of reducing diversity in practice. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

9

4. Fair Value of Financial Assets and Liabilities — Derivative Instruments

ASC Topic 820, *Fair Value Measurement* (ASC 820), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC Topic 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2—Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is the greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis include common stock warrants, embedded derivatives related to the Company's redeemable convertible preferred stock, and a dilutive financing derivative liability established on April 8, 2016 (see Note 6). During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. The following fair value hierarchy table presents information about each major category of the Company's financial liabilities measured at fair value on a recurring basis:

	Quoted Prices in Active Markets	Significant Other	Significant

	for Identical Items (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Total
September 30, 2016				
Liabilities				
June 2016 offering warrant liability	$ -	$ -	$ 1,267,000	$1,267,000
Dilutive financing derivative liability	-	-	382,000	382,000
Total liabilities	$ -	$ -	$ 1,649,000	$1,649,000
December 31, 2015				
Liabilities				
Series B preferred stock derivative liability	$ -	$ -	$ 1,493,000	$1,493,000
2011 Warrant liability	-	-	6,000	6,000
Total liabilities	$ -	$ -	$ 1,499,000	$1,499,000

There were no transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy for the three and nine months ended September 30, 2016 or the year ended December 31, 2015.

The following table sets forth a summary of changes in the fair value of the Company's derivative and warrant liabilities, which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs:

	Warrant Liability	June 2016 Offering Warrant Liability	Series B Preferred Stock Derivative Liability	Dilutive Financing Derivative Liability
Balance, December 31, 2015	$ 6,000	$ -	$ 1,493,000	$ -
Creation of dilutive financing derivative	-	1,816,000	-	2,282,000
Changes in estimated fair value	(6,000)	(549,000)	(1,493,000)	(355,000)
Payout from liability	-	-	-	(1,545,000)
Balance, September 30, 2016	$ -	$ 1,267,000	$ -	$ 382,000

The fair value of warrant liability related to warrants issued in 2011 on each re-measurement date classified as liabilities is estimated using the Monte Carlo valuation model. For this liability, the Company develops its own assumptions that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company’s common stock, stock price volatility, the contractual term of the warrants, risk–free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. The fair value of this warrant was estimated to be $0 as of September 30, 2016. The following assumptions were used at September 30, 2016 and December 31, 2015:

	September 30, 2016 Series 2011		December 31, 2015 Series 2011	
Volatility	118	%	112	%
Expected term (years)	0.23		0.98	
Risk-free interest rate	0.35	%	0.64	%
Dividend yield	0.00	%	0.00	%
Exercise price	$ 23.00		$ 23.00	
Common stock closing price	$ 1.52		$ 3.98	

The fair value of the June 2016 offering warrants derivative liability on the date of issuance and on each re-measurement date classified as liabilities is estimated using the Black-Scholes valuation model. This method of valuation involves using inputs such as the fair value of the Company’s common stock, stock price volatility, risk–free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level

3 measurement. The following assumptions were used at the June 3, 2016 issuance date and September 30, 2016:

	September 30, 2016	June 3, 2016
Volatility	123 %	123 %
Expected term (years)	4.7	5.00
Risk-free interest rate	1.10 %	1.23%
Dividend yield	0.00 %	0.00%
Exercise price	$ 2.25	$2.25
Common stock closing price	$ 1.52	$2.06

11

The fair value of the Series B preferred stock derivative liability on each measurement date is estimated using the Monte Carlo valuation model. For this liability, the Company develops its own assumptions that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, the expected term of the Series B redeemable convertible preferred stock, risk–free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the Series B redeemable convertible preferred stock conversion liability is considered a Level 3 measurement. On April 8, 2016, all outstanding Series B preferred stock was converted into common stock, and the remaining Series B preferred stock derivative liability balance of $91,000 was reversed and recorded as a gain in derivative liability on the Company's statements of operations in the second quarter of 2016. The following assumptions were used at December 31, 2015:

	December 31, 2015
Volatility	108 to 117%
Expected term (years), weighted average	0.50 to 2.50
Risk-free interest rate	0.49 to 1.19%
Dividend yield	0.00 %
Exercise price	$7.00
Common stock closing price	$3.98

The fair value of the dilutive financing derivative liability on each measurement date is estimated using the Monte Carlo valuation model (see Note 6). For this liability, the Company develops its own assumptions that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, expected future financings, risk–free interest rates and dividend yields. Due to the nature of these inputs, the valuation of future potential dilutive financings is considered a Level 3 measurement. The following assumptions were used to value the dilutive financing derivative liability from the inception date of April 8, 2016 through September 30, 2016:

Volatility	108 to 121%
Expected term (years), weighted average	1.75 to 2.23
Risk-free interest rate	0.58 to 0.79%
Dividend yield	0.00 %
Stock price dilutive limit	$2.35 to $4.05
Common stock closing price	$1.52 to $3.68

The dilutive financing derivative liability was recorded on the accompanying consolidated balance sheet at its initial value on April 8, 2016 and is marked-to-market at each balance sheet date until the liability is relieved (see Note 6).

As of September 30, 2016, all of the Company's derivative liabilities were marked-to-market with the changes in fair value recorded as a component of change in fair value of derivative liabilities on the Company's consolidated statements of operations.

5. Net Loss per Common Share

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Basic and diluted net loss per common share calculation:				
Net (loss) income	$(2,375,000)	$5,439,000	$(9,338,000)	$1,715,000
Excess of fair value of consideration transferred on conversion of Series B redeemable convertible preferred stock	(1,214,000)	-	(3,580,000)	-
Accretion of Series B redeemable convertible preferred stock	-	(7,163,000)	(1,858,000)	(9,329,000)
Net (loss) income attributable to common stockholders - basic	$(3,589,000)	$(1,724,000)	$(14,776,000)	$(7,614,000)
Changes in fair value of June 2016 Warrants	-	-	(549,000)	-
Net (loss) income attributable to common stockholders - diluted	$(3,589,000)	$(1,724,000)	$(15,325,000)	$(7,614,000)
Weighted average common shares outstanding - basic	11,120,394	5,813,063	8,590,772	5,247,508
Net loss per share of common stock - basic	$(0.32)	$(0.30)	$(1.72)	$(1.45)
Weighted average common shares outstanding - diluted	11,120,394	5,813,063	8,648,914	5,247,508
Net loss per share of common stock - diluted	$(0.32)	$(0.30)	$(1.77)	$(1.45)

The numerator for the diluted loss per share for the three and nine months ended September 30, 2016, has been increased by $0 and $549,000, respectively, due to a gain associated with the Company's June 2016 offering warrant liability.

The following outstanding securities at September 30, 2016 and 2015 have been excluded from the computation of diluted weighted shares outstanding for the three and nine months ended September 30, 2016 and 2015, as they would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Options	736,938	631,126	736,938	631,126
Warrants	2,443,478	742,604	1,379,648	656,196
Series B redeemable convertible preferred stock	-	150,557	-	150,557
Total	3,180,416	1,524,287	2,116,586	1,437,879

6. Redeemable Convertible Preferred Stock

On June 13, 2013, the Company's Board of Directors approved a resolution designating 9,357,935 shares of Preferred Stock as Series B redeemable convertible preferred stock (Series B) with an initial stated value of $1.40 and par value of $0.01 per share. As of April 7, 2016, each Series B share was convertible into 0.20 shares of common stock and was entitled to the number of votes equal to the number of shares of common stock into which such Series B share could be converted. The Series B shares were convertible into common stock by the holder of the shares at any time. The Series B shares were subject to automatic conversion into common stock upon the election of the holders of at least two-thirds of the outstanding Series B shares. In addition, pursuant to the Company's Articles of Incorporation, the Series B shares were automatically convertible into common stock upon the occurrence of an underwritten initial public offering by the Company that satisfied certain conditions. Holders of the Series B shares were entitled to receive cumulative, cash dividends at the rate of 10% of the Series B stated value. Such dividends accrued from day-to-day commencing on the original issue date, whether or not earned or declared by the Board of Directors, and were compounded annually. The Series B shares were redeemable by the Company at any time on or after June 26, 2018, upon the election of the holders of at least two-thirds of the outstanding Series B shares for an amount equal to the original issue price per share plus any accrued and unpaid dividends. Holders of the Series B shares were entitled to a liquidation preference in an amount equal to the Series B stated value of $1.40 per share plus all accrued and unpaid dividends in the event of a liquidation, dissolution, or winding-up of the Company, or in the event of a merger or acquisition of the Company. In connection with the private placement of Series B shares, the Company recorded a liability for an embedded derivative that required bifurcation under the applicable accounting guidance. The embedded derivative included a redemption feature, multiple dividend features, as well as multiple conversion features with specified anti-dilution adjustments for certain financing transactions involving the issuance of securities at a price below a minimum issuance price of $7.00 per share.

As of April 7, 2016, the Company had accreted $1,868,000 from additional paid-in capital to Series B redeemable convertible preferred stock to adjust the redemption value of the Series B to actual at that date.

On April 8, 2016, certain holders of over two-thirds of the Company's then-outstanding shares of the Series B stock (the "Holders") elected to automatically convert all outstanding shares of Series B into shares of common stock in accordance with Section 4.4.4(b)(ii) of the Company's Amended and Restated Articles of Incorporation (the "Conversion"). As a result of the Conversion, the 7,527,853 shares of Series B outstanding as of immediately prior to the Conversion were converted into an aggregate of 1,505,560 shares of common stock.

On April 8, 2016, the Company entered into a Common Stock Issuance Agreement (the "CSIA") with the Holders pursuant to which the Company agreed to issue the Holders an aggregate of 853,465 shares of the Company's common stock. Pursuant to the CSIA, the Company and the Holders also agreed to amend the common stock warrants previously issued to the Holders in June 2013 in order to reduce the exercise price of such warrants from $7.00 per share to $4.05 per share and extend the expiration date thereof from June 26, 2018 to March 31, 2021 (the "Warrant Amendments"). As consideration for the shares and the Warrant Amendments, the Holders waived their right to receive approximately $2.2 million in aggregate cash payments to which they were entitled upon the Conversion in respect of accrued dividends on their former shares of Series B. The Holders also waived their registration rights with respect to certain future registration statements that may be filed, and certain future public offerings that may be conducted, by the Company.

The transaction was accounted for based on the difference between the fair value of the consideration transferred to the Holders of the preferred stock and the carrying amount of the preferred stock on April 7, 2016.

The terms of the CSIA provide that if, after the date of the CSIA, the Company conducts one or more bona fide equity financings in which it sells shares of common stock or preferred stock at a price less than $4.05 per share (each, a "dilutive financing"), the Company will be required to issue to the Holders additional shares of common stock based on a specified formula until the obligation expires. The obligation to issue additional shares in the event of any such dilutive financing (i) only applies to the lowest priced financing conducted after the date of the CSIA, (ii) is subject to limitations under applicable NYSE MKT rules relating to the issuance of additional shares in a private placement at a price less than the greater of book or market value and (iii) will expire at such time the Company has raised $10.0 million in gross proceeds from the sale of common stock and/or preferred stock in a bona fide financing or financings or June 30, 2018, whichever occurs first.

On June 3, 2016, the Company completed a registered public offering of shares of common stock and warrants at a combined per share purchase price of $2.35, resulting in aggregate gross proceeds of $5.0 million (see Note 8). The offering qualified as a dilutive financing under the terms of the CSIA. As a result of the offering, the threshold per share sale price to trigger the Company's obligation to issue additional shares in connection with a future dilutive financing effectively decreased from $4.05 to $2.35.

On June 20, 2016, the Company obtained stockholder approval for the issuance of up to 1,037,053 shares of common stock to the Holders to the extent required by the terms of the CSIA in connection with one or more dilutive financings completed subsequent to the agreement date. Subsequent to the June 2016 financing and as of September 30, 2016, the maximum number of shares the Company could issue to the Holders pursuant to a future dilutive financing was 286,846 shares under the rules of the NYSE MKT. The Company may be contractually required to issue additional shares for no consideration in excess of the maximum number of shares it is currently permitted to issue. The actual number of shares that the Company will be required to issue to the Holders pursuant to the provisions of the CSIA in connection with the closing of a future dilutive financing will depend on the actual price per share of common stock at that such financing. The Company may not be able to comply with its contractual obligation to issue these additional shares.

The CSIA requires the delivery of shares in the event of a future dilutive financing. The Company determined this was a conditional forward contract and recorded a derivative liability as of April 8, 2016 in the amount of $2.3 million for potential future dilutive financings. On June 3, 2016, the future financing derivative liability was adjusted by the fair value of the dilutive shares issuable of $1.5 million as a result of the June offering. The derivative liability was marked-to-market as of September 30, 2016, resulting in a gain of $988,000 and $355,000 to change in fair value of derivative liabilities for the three and nine months ended September 30, 2016, respectively.

The September 30, 2016 consolidated balance sheet reflects dividends payable of $953,000 to former holders of preferred stock, which are classified as current liabilities.

7. Warrants

On January 4, 2016, the Company entered into an Asset Purchase Agreement with Novolytics Limited (the “Purchase Agreement”), to purchase certain preclinical materials and intangible assets, including patent rights, from Novolytics, an unrelated third party. In consideration for the assets acquired, the Company paid cash consideration of approximately $205,000 and issued warrants to purchase an aggregate of 170,000 shares of the Company’s common stock. The warrants have an exercise price of $12.00 per share and contain certain registration rights. The fair value of the warrants issued was $204,000, based on a Monte Carlo valuation model and are classified as equity within the consolidated balance sheets. The Company expensed the total value provided for the acquired assets of $409,000 as in-process research and development as of the acquisition date given there was no alternative future use of the acquired assets due to the early stage nature of the technology and pre-clinical materials.

On April 8, 2016, the Company modified 315,244 warrants held by the Holders, in accordance with the terms of the CSIA (see Note 6).

On June 3, 2016, the Company issued warrants exercisable for an aggregate of 1,063,830 shares of common stock at an exercise price of $2.25 per share in connection with the closing of a registered public offering of common stock and warrants (see Note 8).

The following table provides a summary of warrants outstanding, issued or exercised for the nine months ended September 30, 2016. Also included is the average exercise price per share and the aggregate proceeds to the Company if exercised as of September 30, 2016.

	$2.25		**$4.05 - $8.25**		**$10.75 - $23.00**		**Totals**	
	Shares	**Weighted Average Exercise Price**	**Shares**	**Weighted Average Exercise Price**	**Shares**	**Weighted Average Exercise Price**	**Shares**	**Weighted Average Exercise Price**
Balance, December 31, 2015	-	$-	694,062	$5.82	515,587	$11.39	1,209,649	$8.19
Issuances	1,063,830	2.25	-	-	170,000	12.00	1,233,830	3.59
Exercises	-	-	-	-	-	-	-	-
Balance, September 30, 2016	1,063,830	$2.25	694,062	$5.82	685,587	$11.54	2,443,479	$5.87
Aggregate proceeds if exercised	$2,393,618		$4,036,474		$7,914,572		$14,344,664	

8. Stockholders' Equity

On May 31, 2016, the Company entered into a Securities Purchase Agreement (the "SPA") with certain purchasers providing for the sale and issuance in a registered public offering of an aggregate of 2,127,660 shares of the Company's common stock and warrants to purchase 1,063,830 shares of the Company's common stock. Each share of

common stock was sold together with a warrant to purchase 0.50 of a share of common stock at a combined purchase price of $2.35 per unit, for aggregate gross proceeds to the Company of $5.0 million. The offering closed on June 3, 2016. The warrants have an exercise price of $2.25 per share, were exercisable immediately upon issuance and expire five years following the date of issuance. The Company received net proceeds from the offering of approximately $4.2 million after deducting placement agent fees and other offering expenses payable by the Company.

Pursuant to a Placement Agent Agreement dated May 31, 2016, by and between the Company and Roth Capital Partners, LLC (“Roth”) and Griffin Securities, Inc. (“Griffin”), Roth and Griffin acted as co-placement agents for the offering. The Company agreed to pay an aggregate cash fee for placement agent services equal to 7% of the gross proceeds of the offering (the “Placement Agent Fee”), as well as a non-refundable legal reimbursement fee of $75,000.

The Company evaluated the warrants issued in the offering and determined the warrant instruments do not qualify for the scope exception in ASC 815, due to certain net cash settlement provisions in the warrant agreement. The Company recorded a derivative liability for the estimated fair value of the warrants issued in connection with the offering in the amount of $1.8 million (based on a Black-Scholes Option Pricing Model assuming no dividend yield, volatility of 123%, and a risk-free interest rate of 1.23%). The remaining balance of $3.2 million, after deducting for the fair value of the warrants, was allocated to the value of the common stock. Offering costs directly allocable to the offering totaled $0.8 million, including placement agent fees and legal expenses. Of this amount, $0.2 million was allocable to the warrants and recorded as other expense on the Company’s consolidated statements of operations based on the relative fair value of the warrants to the common stock.

The derivative liability for the warrants was marked-to-market at September 30, 2016, with the decrease in fair value of $549,000 recorded as a component of change in fair value of derivative liability on the Company’s Statements of Operations (see Note 4).

On March 16, 2015, the Company issued and sold 1,575,758 shares of common stock in a private placement at a price of $8.25 per share, for aggregate proceeds of $13.0 million. In conjunction with this private placement, the Company issued warrants to purchase an aggregate of 393,939 shares of common stock at an exercise price of $10.75 per share to the purchasers of the common stock. The Company paid $833,000 in fees to its placement agents, along with the issuance of warrants to purchase an aggregate of 94,545 shares of common stock at an exercise price of $10.75 per share. The Company valued these warrants as liability instruments and recorded a liability of $4,210,000 as of March 16, 2015. In the first quarter of 2015, the Company recorded $213,000 of other expenses representing the portion of the initial warrant value of the placement agent warrants related to the initial fair value of the warrants issued to the purchasers of the common stock. The remainder of the initial fair value of the warrants of $3,996,000 was treated as a reduction of additional paid-in-capital. In addition, $218,000 of the fees paid to a placement agent were expensed as other expenses in the six months ended June 30, 2015 as they also represented issuance costs related to the initial fair value of the warrants issued to the purchasers of the common stock.

9. Stock-Based Compensation

Share-based Compensation

In June 2016, the Company's stockholders approved the 2016 Equity Incentive Plan (the 2016 Plan). The plan provides for the issuance of incentive awards in the form of non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance-based stock awards. The awards may be granted by the Company's Board of Directors to its employees, directors and officers and to consultants, agents, advisors and independent contractors who provide services to the Company or to a subsidiary of the Company. The exercise price for stock options must not be less than the fair market value of the underlying shares on the date of grant. Stock options expire no later than ten years from the date of grant and generally vest and typically become exercisable over a four-year period following the date of grant. Upon the exercise of stock options, the Company issues the resulting shares from shares reserved for issuance under the 2016 Plan. With the approval of the 2016 Plan, the remaining unallocated shares under the Company's 2013 Stock Incentive Plan were allocated to the 2016 Plan and an additional 1,000,000 new shares were added to the authorized share reserve under the 2016 Plan.

The Company accounts for stock options and restricted stock units related to its stock incentive plans under the provisions of ASC 718, which requires the recognition of the fair value of stock-based compensation. The fair value of stock options was estimated using a Black-Scholes option valuation model. This model requires the input of subjective assumptions in implementing ASC 718, including expected dividend, expected life, expected volatility and forfeiture rate of each award, as well as the prevailing risk-free interest rate and the fair value of the underlying common stock on the date of grant. The fair value of equity-classified awards is amortized over the vesting period of the award, and the Company has elected to use the straight-line method of amortization. The assumptions used in the Black-Scholes option valuation model for the three months ended September 30, 2016 are set forth below.

- *Expected Dividend*: The Company does not anticipate paying any dividends on its common stock.
- *Expected Life*: The expected life represents the period that the Company expects its stock-based awards to be outstanding. The Company's expected life assumption was based on the simplified method set forth in the SEC Staff Accounting Bulletin 110. The Company's estimation of the expected life for stock options granted to parties other than employees or directors is the contractual term of the option award.
- *Expected Volatility:* Expected volatility is the measure by which the Company's stock price is expected to fluctuate during the expected term of an option. The Company's expected volatility represents the weighted average historical volatility of the shares of its common stock.
- *Risk-Free Interest Rate*: The Company bases the risk-free interest rate used on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term. Where the expected term of its stock-based awards does not correspond with the terms for which interest rates are quoted, the Company performs a straight-line interpolation to determine the rate from the available term maturities.
- *Forfeiture Rate*: The Company applies an estimated forfeiture rate that is derived from historical shares forfeited prior to vesting. If the actual number of forfeitures differs from our estimates, the Company may record additional adjustments to compensation expense in future periods.

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock option grants were as follows for the nine months ended September 30, 2016:

	September 30, 2016
Risk-free interest rate	1.22 - 1.63%
Expected volatility	113 - 123%
Expected term (in years)	6.0
Expected dividend yield	0.0%

Stock-based compensation expense is reduced by an estimated forfeiture rate derived from historical employee termination behavior. If the actual number of forfeitures differs from the Company's estimates, the Company may record adjustments to increase or decrease compensation expense in future periods.

The estimated grant-date fair value of the Company's stock-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized for the three and nine months ended September 2016 and September 30, 2015 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016 (Unaudited)	2015 (Unaudited)	2016 (Unaudited)	2015 (Unaudited)
Research and development	$37,000	$ 29,000	$89,000	$ 88,000
General and administrative	297,000	120,000	1,609,000	165,000
Total stock-based compensation	$334,000	$ 149,000	$1,698,000	$ 253,000

The following table summarizes stock option activity for the nine months ended September 30, 2016:

		Options Outstanding			
	Shares Available **For Grant**	**Shares**	Weighted Average Exercise **Price**	Average Remaining Contractual Term **(Years)**	Intrinsic **Value**
Balance, December 31, 2015	723,431	669,769	$ 8.68	9.29	$ -
Granted	(231,208)	231,208	2.82	-	-
Exercised	-	-	-	-	-
Forfeited/Cancelled	158,856	(158,856)	8.86	-	-
Expired	1,083	(5,183)	12.72	-	-
Shares authorized	1,000,000	-	-	-	-
Balance, September 30, 2016	1,652,162	736,938	$ 6.78	8.60	$ -
Vested or expected to vest at September 30, 2016		626,777	$ 7.10	8.50	$ -
Exercisable at September 30, 2016		179,501	$ 8.76	7.15	$ -

The intrinsic value of options exercisable as of September 30, 2016 was $0.0, based on the Company's closing stock price of $1.52 per share and the exercise price of the options.

During the nine months ended September 30, 2016, the Company issued 231,208 common stock options to its employees and an executive with an average exercise price of $2.82 per share. Included in this amount were 99,919 stock options, with an exercise price of $2.85, to its Chief Financial Officer, pursuant to his employment agreement dated January 18, 2016. During the three and nine months ended September 30, 2015, the Company issued 547,181 common stock options to its executives and board members with an average exercise price of $8.72 per share, including 399,716 stock options, with an exercise price of $9.45, to its Chief Executive Officer.

As of September 30, 2016, there was $1.9 million of total unrecognized compensation expense related to unvested stock options, which the Company expects to recognize over the weighted average remaining period of 2.74 years.

Shares Reserved For Future Issuance

As of September 30, 2016, the Company had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Stock options outstanding	736,938
Employee stock purchase plan	120,000
Available for future grants under the 2016 Plan	1,652,162
Warrants	2,443,479
Total shares reserved	4,952,579

Employee Stock Purchase Plan (ESPP)

On June 20, 2016, the Company's stockholders approved the Company's 2016 Employee Stock Purchase Plan (the "ESPP"). The ESPP allows eligible employees on a voluntary basis to purchase shares of the Company's common stock. The shares are sold to participants at a price equal to the lesser of 85% of the fair market value of the Company's common stock at the (i) beginning of the six month offering period, or (ii) end of the six month purchase period. The ESPP provides for four six month purchase periods during each 24 month term. The initial shares provided for under the plan are 120,000, and automatically increase annually as allowed for under the ESPP, beginning January 1, 2017 and through January 1, 2026.

As of September 30, 2016, no shares have been issued under the ESPP.

10. Collaborative and Other Agreements

In June 2013, the Company entered into a Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research. The Collaborative Research and Development Agreement is focused on developing and commercializing bacteriophage therapeutics to treat *S. aureus* infections. During the three and nine months ended September 30, 2016 and 2015, the Company recorded no payments to Walter Reed Army Institute of Research under the Collaborative Research and Development Agreement.

In March 2013, the Company entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation (the “ECC Agreement”). This agreement allowed the Company to utilize Intrexon’s synthetic biology platform for the identification, development and production of bacteriophage-containing human therapeutics. The Company paid a one-time technology access fee in 2013 to Intrexon of $3,000,000 in common stock. Pursuant to the agreement, the Company was required to pay Intrexon, in cash or stock, milestone fees of $2,500,000 for the initiation and commencement of the first Phase 2 trial and $5,000,000 upon the first regulatory approval of any product in any major market country. With regard to each product sold by the Company, the Company was required to pay, in cash, tiered royalties on a quarterly basis based on net sales of AmpliPhi Products, calculated on a product-by-product basis. No milestones have been met and no milestone payments have been paid to Intrexon through September 30, 2016. During the three and nine months ended September 30, 2016, the Company recorded $0 and $76,000, respectively, in expenses under the Exclusive Channel Collaboration Agreement, with cash payments totaling $0 and $117,000, respectively. During the three and nine months ended September 30, 2015, the Company recorded $37,000 and $81,000, respectively, in expenses under the Exclusive Channel Collaboration Agreement, with cash payments for the three and nine months ended September 30, 2015 totaling $40,000 and $75,000, respectively. On April 13, 2016, the Company provided written notice to Intrexon of its election to voluntarily terminate the ECC Agreement. The effective date of the termination was July 12, 2016. As of September 30, 2016, the Company had a liability of $15,000 recorded for amounts due to Intrexon. The Company did not incur any early termination penalties as a result of the termination of the ECC Agreement.

In April 2013, the Company entered into a collaboration agreement with the University of Leicester to develop a phage therapy that targets and kills all toxin types of *C. difficile.* In August 2013, the Company entered into a collaboration agreement with both the University of Leicester and the University of Glasgow to carry out certain animal model development work. Under these agreements, which are referred to collectively as the Leicester Development Agreements, the Company provides payments to the University of Leicester to carry out *in vitro* and to the University of Glasgow to carry out animal model development work on the University of Leicester's development of a bacteriophage therapeutic to resolve *C. difficile* infections. The Company licensed related patents, materials and know-how from the University of Leicester. Under the Leicester Development Agreements, the University of Leicester will provide the bacteriophage and act as overall project coordinator for the development work. All rights, title and interest to any intellectual property developed under the Leicester Development Agreements belong to the Company. Under the Leicester License Agreement, the Company has exclusive rights to certain background intellectual property of the University of Leicester, for which it will pay the University of Leicester royalties based on product sales and make certain milestone payments based on product development. The Company renewed this collaboration in November 2015. This agreement expires November 12, 2018. During the three and nine months ended September 30, 2016, the Company recorded $41,000 and $127,000, respectively, in expenses to the University of Leicester under the Leicester Development Agreements, with cash payments totaling $0 and $140,000, respectively. During the three and nine months ended September 30, 2015, the Company recorded $68,000 and $156,000, respectively, in expenses to the University of Leicester under the Leicester Development Agreements, with cash payments in the amount of $55,000 and $219,000, respectively. During the three and nine months ended September 30, 2016, the Company recognized no expense and made no payments to the University of Glasgow under the Leicester Development Agreements. During the three and nine months ended September 30, 2015, the Company recorded $0 and $13,000, respectively in expenses to the University of Glasgow under the Leicester Development Agreements, with cash payments totaling $0 and $61,000, respectively.

In September 2015, the Company entered into a non-exclusive patent license agreement with Takara Bio Inc. (the Takara Agreement). Under this agreement Takara licensed certain patents from the Company related to AAV1 Vector gene delivery systems, for which the Company is an exclusive licensor with the University of Pennsylvania. The Company received a $40,000 non-refundable, up-front licensing payment and is entitled to receive royalties from Takara of 12.0% of net license product sales and 6.0% of service revenues associated with the licensed products. The agreement calls for minimum annual royalties of $15,000 commencing on February 28, 2016. In addition, the Takara Agreement provides milestone fees to the Company of $30,000 of the first $1,000,000 of licensed product revenues by Takara and an additional $40,000 when cumulative net sales of the licensed product by Takara exceed $2,000,000. During the three and nine months ended September 30, 2016 the Company recognized revenue of $4,000 and $11,000, respectively, under the Takara Agreement.

11. Legal Proceedings

On April 14, 2016, NRM VII Holdings I, LLC ("NRM"), filed a complaint against the Company and the current members of the Company's Board of Directors in the Superior Court of California, County of San Diego, which complaint was amended on July 25, 2016. NRM, together with its affiliates, is one of the principal stockholders of the Company. The amended complaint (the "complaint") alleges that the Company breached the implied covenant of good

faith and fair dealing by entering into an alleged scheme to force NRM to convert its Series B Shares into shares of common stock. The complaint further alleges that the members of the Board who are named as defendants breached their fiduciary duty of good faith and loyalty owed to NRM, as one of the Company's stockholders, by participating in this alleged scheme. The complaint seeks unspecified monetary damages and other relief. The Company plans to vigorously defend against the claims advanced.

The Company determines whether it should accrue an estimated loss for a contingency in a particular legal proceeding by assessing whether a loss is deemed probable and whether the amount can be reasonably estimated. Claim estimates that are probable and can be reasonably estimated are reflected as liabilities. Legal proceedings are inherently unpredictable and the matters in which the Company may be involved often will present complex legal and factual issues. Because of the uncertainties related to the Company's pending litigation, investigations, inquiries or claims, management is currently unable to predict the ultimate outcome of any litigation, investigation, inquiry or claim, determine whether a liability has been incurred, or make an estimate regarding the possible loss or range of loss that could result from an unfavorable outcome. It is reasonably possible that some of the matters which may be asserted could be decided unfavorably to the Company. An adverse ruling or outcome in any lawsuit involving the Company could materially affect its business, liquidity, consolidated financial position or results of operations. In view of the unpredictable nature of such matters, the Company cannot provide any assurances regarding the outcome of any litigation, investigation, inquiry or claim to which it is a party of the impact on the Company of an adverse ruling on such matters.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q, and the audited financial statements and notes thereto as of and for the year ended December 31, 2015 included in our Annual Report on Form 10-K filed with the SEC.

Statements contained in this report that are not statements of historical fact are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, without limitation, statements concerning product development plans, the use of bacteriophages to kill bacterial pathogens, having resources sufficient to fund our operations through the end of 2016, future funding sources, general and administrative expenses, clinical trial and other research and development expenses, capital resources, capital expenditures, tax credits and carry-forwards, and additional financings and litigation-related matters. Words such as "believe," "anticipate," "plan," "expect," "intend," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. These statements are subject to risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. These forward-looking statements speak only as of the date on which they were made, and we undertake no obligation to update any forward-looking statements.

Overview

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Phage therapeutics use bacteriophages, a family of viruses, to kill pathogenic bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacteria. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current therapies including the so-called multi-drug-resistant or "superbug" strains of bacteria.

Our goal is to be the leading developer of phage therapeutics. We are combining our expertise in the manufacture of drug-quality bacteriophages and our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of collaboration partners in bacteriophage biology, synthetic biology and manufacturing, to develop second-generation bacteriophage products.

Our lead product candidate is AB-SA01 for the treatment of *S. aureus* infections, including methicillin-resistant *S. aureus*, or MRSA. We also have AB-PA01 for the treatment of *P. aeruginosa* infections in development, and AB-CD01 for the treatment of *C. difficile* infections in preclinical development.

We have generally incurred net losses since our inception and our operations to date have been primarily limited to research and development and raising capital. Since the shift in our focus to novel therapeutics in February 2011 through September 30, 2016, we have received approximately $46.1 million in net proceeds from the issuance of our equity securities and convertible debt securities. As of September 30, 2016, we had an accumulated deficit of $371.9 million. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and obtaining regulatory approval of our product candidates.

We currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates and for working capital and other general corporate purposes.

We expect our research and development expenses to increase for the foreseeable future as we continue development of our product candidates. We also expect to incur additional expenses associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete development and obtain marketing approval for at least one of our product candidates.

We may also use a portion of our existing cash and cash equivalents for the potential acquisition of, or investment in, product candidates, technologies, formulations or companies that complement our business, although we have no current understandings, commitments or agreements to do so. Our existing cash and cash equivalents will not be sufficient to enable us to complete all necessary development of any potential product candidates. Accordingly, we will be required to obtain further funding through one or more other public or private equity offerings, debt financings, collaboration or licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of assets, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations and result in a loss of investment by our stockholders.

Recent Events

In October 2016, the Company received a tax incentive payment from the Australian tax authority, in the amount of approximately $0.9 million. Such tax incentive is based on eligible expenses for research and development activities incurred by our Australian subsidiary in 2015. This payment will be recorded in the fourth quarter of 2016 as a reduction to research and development expenses.

In October 2016, we announced topline results from the Phase 1 trial to evaluate the safety and tolerability of AB-SA01, our proprietary investigational phage cocktail targeting *Staphylococcus aureus* (*S. aureus*) infections in patients suffering from chronic rhinosinusitis (CRS). Enrollment in the trial has been completed and the Safety Monitoring Committee overseeing the trial has determined that AB-SA01 was well-tolerated by all nine patients and that there were no drug-related serious adverse events. The Phase 1 clinical trial was initiated in January 2016 and is being conducted at the Queen Elizabeth Hospital in collaboration with the University of Adelaide and Flinders University. The primary outcome of eradication of *S. aureus* was achieved in two of the three patients in Cohort 2 and zero of three patients in Cohort 1. In both Cohorts 1 and 2, patients reported improvements in symptoms, as measured on days 0, 7 and 14 by Visual Analogue Scale (VAS) and Sino-Nasal Outcome Test (SNOT-22) score. In Cohort 2, there were no improvements post treatment in endoscopic video examinations using the Lund Kennedy Score. The complete study report is expected by the end of 2016.

In September 2016, we announced topline data from our Phase 1 trial to evaluate the safety and tolerability of AB-SA01 when administered topically to the intact skin of healthy adults. We initiated the double-blind, placebo-controlled study in May 2016 under a U.S. investigational new drug application, or IND. Twelve healthy adult volunteers between the ages of 18 and 60 participated in the trial and were split into two cohorts of six participants each, and received either the low-dose or high-dose of AB-SA01, administered topically to the forearm under an occlusive bandage. Placebo was similarly administered to the volunteer’s opposite forearm, allowing each participant to serve as his or her own control. Participants received AB-SA01 and placebo daily for three consecutive

days and were monitored following treatment. A safety committee reviewed the trial data and concluded that AB-SA01 was well tolerated by subjects in the trial and there were no drug-related serious adverse events. The complete study report is expected by the end of 2016.

Results of Operations

Comparison of three and nine months ended September 30, 2016 and 2015

Revenue

For the three and nine months ended September 30, 2016 we recognized $0.03 million and $0.2 million, respectively, in revenue related to our former gene therapy program, compared with $0.1 million and $0.3 million for the three and nine months ended September 30, 2015, respectively.

Research and Development Expenses

Research and development expenses for the quarter ended September 30, 2016 totaled $1.7 million compared to $0.7 million for the same period of 2015. The increase of $1.0 million was primarily related to increased personnel costs as well as clinical expenses, offset by research and development tax incentive received during the three months ended September 30, 2015 which was recorded as an offset to research and development expenses.

Research and development expenses for the nine months ended September 30, 2016 totaled $4.9 million compared to $2.8 million incurred in the same period of 2015. This increase of $2.1 million was primarily related to higher compensation costs of $0.6 million, $0.2 million of professional recruiting fees, and $0.4 million for the expense recorded related to the assets acquired from Novolytics.

We anticipate that research and development expenses will remain relatively flat in the fourth quarter of 2016 as compared to the third quarter of 2016, but may increase in future periods as we initiate non-clinical research studies, hire additional research and development staff, initiate new clinical trials, and continue our discovery efforts.

General and Administrative Expenses

General and administrative expenses for the quarter ended September 30, 2016 were $1.8 million compared to $1.8 million for the same period of 2015. General and administrative expenses for the three months ended September 30, 2016 included an increase of $0.3 million in compensation cost, primarily stock based compensation for awards granted to two executives, compared with the same period last year, which was offset by a $0.3 million severance charge for the three months ended September 30, 2015.

General and administrative expenses for the nine months ended September 30, 2016 were $6.9 million compared to $4.9 million for the same period of 2015. The $2.0 million increase was primarily attributable to $1.9 million of compensation, including $1.4 million of non-cash stock-based compensation related to two new executives, $0.1 million for professional recruitment fees and $0.1 million in increased director compensation, offset by a $0.3 million severance charge for the nine months ended September 30, 2015.

We expect our general and administrative expenses to remain relatively flat in the remainder of 2016 as compared to the third quarter of 2016.

Other Income (Expense)

We recorded a gain of $1.0 million for the three months ended September 30, 2016 related to the change to the fair value of our derivative liabilities. The gain was the result of a gain of $44,000 related primarily to the change in fair value of our derivative liability for warrants issued in June 2016 and a gain of $1.0 million related to the change in fair value of our dilutive financing derivative liability.

We recorded a gain of $2.4 million for the nine months ended September 30, 2016 related to the change to the fair value of our derivative liabilities. The gain was the result of a gain of $0.6 million related primarily to the change in fair value of our derivative liability for warrants issued in June 2016, a gain of $1.5 million related to the change in fair value of our Series B preferred stock derivative liability, and a gain of $0.4 million related to the change in fair value of our dilutive financing derivative liability established during the quarter ended June 30, 2016.

We recorded a gain of $7.7 million for the three months ended September 30, 2015 related to the change to the fair value of our derivative liabilities. The gain consisted of $0.7 million related to the change in fair value of our derivative liability for warrants issued in 2011, and a gain of $7.0 million related to the change in fair value of our Series B preferred stock derivative liability.

We recorded a gain of $9.3 million for the nine months ended September 30, 2015 related to the change to the fair value of our derivative liabilities. The gain consisted of $0.6 million related to the change in fair value of our derivative liability for warrants issued in 2011, and a gain of $8.7 million related to the change in fair value of our Series B preferred stock derivative liability.

We will continue to adjust the liability related to our outstanding warrant derivative liabilities to fair value until the earlier of exercise or expiration of the warrants or until terms of the warrants no longer require them to be accounted for as liability instruments. We will continue to adjust the liability related to our dilutive financing derivative until the obligation to issue additional shares in the event of a future dilutive financing is met or expires.

For the nine months ended September 30, 2016, we recorded expenses of $0.2 million consisting of placement agent fees and other offering costs from our June 2016 registered public offering of common stock and warrants. We recorded expenses of $0.4 million for the nine months ended September 30, 2015 consisting of placement agent costs from our March 2015 private placement of common stock, which related to placement agent fees and the initial fair value of warrants issued to the placement agents.

Liquidity and Capital Resources

We have incurred net losses since inception through September 30, 2016 of $371.9 million, of which $315.5 million was incurred as a result of our prior focus on gene therapy in fiscal years 2010 and earlier. We have not generated any product revenues and do not expect to generate revenue from product candidates in the near term.

We had cash and cash equivalents of $4.0 million and $9.4 million at September 30, 2016 and December 31, 2015, respectively. In October of 2016, we received a tax incentive payment of $0.9 million from the Australian tax authority.

Net cash used in operating activities for the nine months ended September 30, 2016 was $9.1 million, as compared to $7.5 million for the nine months ended September 30, 2015. Net loss recorded during the nine months ended September 30, 2016 was $9.3 million, inclusive of a $2.4 million non-cash gain on derivative liabilities. Net income recorded during the nine months ended September 30, 2015 was $1.7 million, inclusive of a $9.3 million non-cash gain on derivative liability. The net increase in cash used in operating activities of $1.6 million, in addition to the effect of the non-cash gain in derivative liability noted above, is primarily related to an increase in research and development efforts, compensation costs, as well as an increase in professional services.

Net cash used in investing activities was $0.3 million and $0.2 million for the nine months ended September 30, 2016 and September 30, 2015, respectively, and was primarily attributable to purchases of property and equipment.

Cash provided by financing activities for the nine months ended September 30, 2016 was primarily comprised of net proceeds of $4.2 million from the June 2016 offering of common stock and warrants to purchase common stock, after deducting placement agent fees and other expenses related to the issuance of approximately $0.8 million. Cash provided by financing activities for the nine months ended September 30, 2015 was comprised of gross proceeds of $13.0 million from the March 2015 private placement of common stock and warrants to purchase common stock, less commissions and other expenses related to the issuance of approximately $0.6 million.

We will need to raise additional capital to continue to fund our future operations. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

We may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financings;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

We believe our existing resources are sufficient to fund our planned operations through the end of 2016. This estimate is based on our current product development timelines, projected staffing expenses, working capital requirements, and capital expenditure plans.

Our ability to raise additional funds will depend in part on the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as, factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on acceptable terms. If we are unable to secure additional funds on a timely basis or on acceptable terms we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment by our stockholders. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in dilution to our existing stockholders.

Off-Balance Sheet Arrangements

As of September 30, 2016, we did not have off-balance sheet arrangements.

Recent Accounting Pronouncements

Refer to *Note 3* of the Condensed Consolidated Notes to the Consolidated Financial Statements contained elsewhere in this report.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

Item 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this report. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective disclosure controls system, misstatements due to error or fraud may occur and not be detected.

Based on this evaluation, our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of the end of the period covered by this report as a result of the material weakness identified in our internal control over financial reporting as of December 31, 2015, as described further below.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Remediation of Material Weakness

As of December 31, 2015, our management identified a material weakness in our internal controls over financial reporting and concluded that, as of such date, we did not maintain adequate and effective internal control in the area of complex and non-routine transactions and in the application of Accounting Standards Codification No. 260, “Earnings Per Share,” and consequently our internal control over financial reporting was not effective at a reasonable assurance level. Based on that conclusion, we continue to review, document and test our internal control over financial reporting. We also continue to take steps to remediate certain identified deficiencies in our internal control over financial reporting as of December 31, 2015 in the area of complex and non-routine transactions. Steps taken during the first nine months of 2016 that resulted in improvements to our internal control over financial reporting included the following:

- the addition of and training of qualified personnel to identify and evaluate complex and non-routine transactions;
- the development of specific procedures for the evaluation, documentation and review of complex and non-routine transactions; and
- continued implementation of standardized financial control and reporting processes.

The remediation actions are being monitored by the Audit Committee of our Board of Directors.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On April 14, 2016, NRM VII Holdings I, LLC ("NRM"), filed a complaint against us and the current members of our Board of Directors in the Superior Court of California, County of San Diego, which complaint was amended on July 25, 2016. NRM, together with its affiliates, is one of our principal stockholders. The amended complaint (the "complaint") alleges that we breached the implied covenant of good faith and fair dealing by entering into an alleged scheme to force NRM to convert its shares of Series B redeemable convertible preferred stock into shares of our common stock. The complaint further alleges that the members of the Board who are named as defendants breached their fiduciary duty of good faith and loyalty owed to NRM, as one of our stockholders, by participating in this alleged scheme. The complaint seeks unspecified monetary damages and other relief. We plan to vigorously defend against the claims advanced.

Claim estimates that are probable and can be reasonably estimated are reflected as liabilities. Because of the uncertainties related to our pending litigation, investigations, inquiries or claims, management is currently unable to predict the ultimate outcome of any litigation, investigation, inquiry or claim, determine whether a liability has been incurred, or make an estimate regarding the possible loss or range of loss that could result from an unfavorable outcome. It is reasonably possible that some of the matters, which are pending or may be asserted, could be decided unfavorably to us. Although we maintain liability insurance coverage to protect our assets from losses arising out of or involving activities associated with ongoing and normal business operations, our insurance may not adequately cover, any liabilities that we incur. An adverse ruling or outcome in any lawsuit involving us could materially affect our business, liquidity, consolidated financial position or results of operations. In view of the unpredictable nature of such matters, we cannot provide any assurances regarding the outcome of any litigation, investigation, inquiry or claim to which we are a party or the impact on us of an adverse ruling of such matters.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below that are marked with an asterisk (*) did not appear as separate risk factors in, or contain changes to the similarly titled risk factors included in, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015. If any of the following risks actually occur, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Financial Condition and Need for Additional Capital

There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations.*

Our financial statements as of September 30, 2016 were prepared under the assumption that we will continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. At September 30, 2016, we had cash and cash equivalents of $4.0 million. Our ability to continue as a going concern depends on our ability to raise substantial additional funds through public or private equity offerings, collaborative or licensing arrangements and/or debt financing.

We will need to raise additional capital to continue operations.*

Our consolidated financial statements for the quarter ended September 30, 2016 were prepared under the assumption that we would continue our operations as a going concern. However, we have had recurring losses from operations, negative operating cash flow and an accumulated deficit.

We do not generate any cash from operations and must raise additional funds in order to continue operating our business. We expect to continue to fund our operations primarily through equity and debt financings in the future. If additional capital is not available to us when needed or on acceptable terms, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely. As of September 30, 2016, we had cash and cash equivalents of $4.0 million. In October of 2016, we received a tax incentive payment of $0.9 million from the Australian tax authority. We believe that our existing resources will be sufficient to fund our

planned operations through the end of 2016.

Developing drugs and conducting clinical trials is expensive. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

We will need to raise additional capital to support our product development activities in the remainder of 2016 and beyond. We may seek funds through arrangements with collaborators or others that may require us to relinquish rights to the products candidates that we might otherwise seek to develop or commercialize independently. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, or at all.

We may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financings;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Raising additional capital through the sale of securities could cause significant dilution to our stockholders. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. In addition, we believe there is currently substantial doubt about our ability to continue as a concern which hinders our ability to raise additional funds in a timely manner and on favorable terms. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

If we are unable to secure additional funds on a timely basis or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will continue to be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to a total loss of investment by our stockholders.

We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain.*

We have incurred losses in each year since our inception in 1992. Prior to our merger with Biocontrol in January 2011, our accumulated deficit was $315.5 million. Since January 2011 through September 30, 2016, we have incurred an accumulated deficit of $56.4 million, and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the three and nine months ended September 30, 2016 we had an operating loss of $3.4 million and $11.5 million, respectively. Additional information regarding our results of operations may be found in our consolidated financial statements and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this report.

Clinical trials and activities associated with discovery research are costly. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

To attain ongoing profitability, we will need to develop products successfully and market and sell them effectively, or rely on other parties to do so. We cannot predict when we will achieve ongoing profitability, if at all. We have never generated revenue from the commercial sales of our product candidates, and there is no guarantee that we will be able to do so in the future. If we fail to become profitable, or if we are unable to fund our continuing losses, our business, financial condition and results of operations may be materially adversely impacted and our stock price could decline.

We have never generated any revenue from product sales and may never be profitable.

Our ability to generate meaningful revenue and achieve profitability depends on our ability, and the ability of any third party with which we may partner, to successfully complete the development of, and obtain the regulatory approvals necessary to, commercialize our product candidates. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. If any of our product candidates fail in clinical trials or if any of our product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by establishing a sales force, marketing and distribution infrastructure, or by collaborating with a partner;
- obtaining market acceptance of any approved products;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other foreign regulatory authorities to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

A complaint has been filed against us and the members of our Board of Directors by one of our principal stockholders.*

On April 8, 2016, certain holders (the "Holders") of over two-thirds of our then-outstanding shares of Series B redeemable convertible preferred stock ("Series B Preferred") elected to automatically convert all outstanding shares of Series B Preferred into shares of Common Stock in accordance with Section 4.4.4(b)(ii) of our Amended and Restated

Articles of Incorporation, as amended (the "Conversion"). As a result of the Conversion, the 7,527,853 shares of Series B Preferred outstanding as of immediately prior to the Conversion were automatically converted into an aggregate of 1,505,560 shares of our common stock. On April 8, 2016, we entered into a Common Stock Issuance Agreement (the "CSIA") with the Holders pursuant to which we issued to the Holders an aggregate of 853,465 shares of our Common Stock (the "Shares") and amended the common stock warrants issued to the Holders pursuant to that certain Subscription Agreement, dated June 25, 2013, in order to reduce the exercise price of such warrants from $7.00 per share to $4.05 per share and extend the expiration date thereof from June 26, 2018 to March 31, 2021 (the "Warrant Amendments"). As consideration for the Shares and the Warrant Amendments, the Holders waived their right to receive approximately $2.2 million in aggregate cash payments to which they were entitled upon the Conversion in respect of accrued dividends on their former shares of Series B Preferred.

On April 14, 2016, NRM VII Holdings I, LLC ("NRM"), which was not a party to the CSIA, filed a complaint against us and each of the current members of our Board of Directors in the Superior Court of California, County of San Diego, which complaint was amended on July 25, 2016. Prior to the Conversion, NRM held approximately 28.5% of our outstanding shares of Series B Preferred. The complaint alleges that we breached the implied covenant of good faith and fair dealing by entering into an alleged scheme to force NRM to convert its Series B Preferred into common stock. The complaint further alleges that the current members of our Board of Directors breached their fiduciary duty of good faith and loyalty owed to NRM, as one of our stockholders, by participating in this alleged scheme. The complaint seeks unspecified monetary damages and other relief. We plan to vigorously defend against the claims advanced.

Litigation is subject to inherent uncertainties, and an adverse result in the matter described above or other matters that may arise from time to time could have a material adverse effect on our business, results of operations and financial condition. Any litigation to which we are subject may be costly and, further, could require significant involvement of our senior management and may divert management's attention from our business and operations. In addition, our share price may be negatively impacted due to the negative publicity, expenses incurred in connection with our defense, management distraction, and/or other factors related to this litigation. In addition, litigation of this nature may negatively impact our ability to attract and retain strategic partners, as well as qualified board members and management personnel.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We are organized in the United States, and we currently have subsidiaries in the United Kingdom, Australia and Slovenia. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Our ability to use our net operating tax loss carryforwards and certain other tax attributes may be limited.*

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"). These limitations apply if an "ownership change," as defined by Section 382 of the Code, occurs. If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership (including in connection with future private or public offerings, as well as changes that may be outside of our control), may

trigger an "ownership change" and, consequently, limitations under Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We have not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple "ownership changes" since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.*

We are required to maintain internal control over financial reporting adequate to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with generally accepted accounting principles. In connection with the restatement of our consolidated financial statements for the second quarter of 2015 and for the quarterly and annual periods of 2014, we determined that we had a material weakness as of December 31, 2014 and December 31, 2015, namely that our internal control over financial reporting, including control over the evaluation and review of complex and non-routine transactions, were not effective. A material weakness means a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the registrant's annual or interim financial statements will not be prevented or detected on a timely basis.

We do not expect that our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Over time, controls may become inadequate because changes in conditions or deterioration in the degree of compliance with policies or procedures may occur. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. As a result, we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future.

We are taking steps to remediate the material weakness in our internal control over financial reporting, including the addition of and training of qualified personnel to identify and evaluate complex and non-routine transactions and the development of specific procedures, processes and internal controls related to complex and non-routine transactions. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all, or that we will be able to maintain effective controls and procedures even if we remediate our material weakness. If we are unable to successfully remediate our material weakness, implement and maintain effective controls and procedures, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the NYSE MKT to implement provisions of the Sarbanes-Oxley Act, imposes significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years following their initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than expected and thereby incur unexpected expenses.

We expect the rules and regulations applicable to public companies to result in us continuing to incur substantial legal and financial compliance costs. These costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business.

Risks Related to Our Business

We are seeking to develop antibacterial agents using bacteriophage technology, a novel approach, which makes it difficult to predict the time and cost of development. No bacteriophage products have been approved in the United States or elsewhere.

We are developing our product candidates with bacteriophage technology. We have not, nor to our knowledge has any other company, received regulatory approval from the FDA or equivalent foreign agencies for a pharmaceutical drug based on this approach. While *in vitro* studies have characterized the behavior of bacteriophages in cell cultures and there exists a body of literature regarding the use of phage therapy in humans, the safety and efficacy of phage therapy in humans has not been extensively studied in well-controlled modern clinical trials. Most of the prior research on phage-based therapy was conducted in the former Soviet Union prior to and immediately after World War II and lacked appropriate control group design or lacked control groups at all. Furthermore, the standard of care has changed substantially during the ensuing decades since those studies were performed, diminishing the relevance of prior claims of improved cure rates. We cannot be certain that our approach will lead to the development of approvable or marketable drugs.

Developing phage-based therapies on a commercial scale will also require developing new manufacturing processes and techniques. We and our third-party collaborators may experience delays in developing manufacturing capabilities for our product candidates, and may not be able to do so at the scale required to efficiently conduct the clinical trials required to obtain regulatory approval of our product candidates, or to manufacture commercial quantities of our products, if approved.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates.

Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval for and commercialize our product candidates.

Delays in our ability to commence or enroll patients for our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our product candidates. Planned clinical trials may not be commenced or completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including:

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- failures in our internal manufacturing operations that result in our inability to consistently and timely produce bacteriophages in sufficient quantities to support our clinical trials;
- the availability of financial resources to commence and complete our planned clinical trials;
- delays in reaching a consensus with clinical investigators on study design;
- delays in reaching a consensus with regulatory agencies on trial design or in obtaining regulatory approval to commence a trial;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials;
- failure by clinical trial sites, other third parties, or us to adhere to clinical trial agreements;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval; and
- adverse safety events experienced during our clinical trials.

If we do not successfully commence or complete our clinical trials on schedule, the price of our common stock may decline.

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the product candidate under study;
- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients from clinical trials for other treatments.

We may experience difficulties in enrolling patients in our clinical trials, which could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations.

We have not completed formulation development of any of our product candidates.

The development of our bacteriophage product candidates requires that we isolate, select and combine a number of bacteriophages that target the desired bacteria for that product candidate. The selection of bacteriophages for any of our product candidates is based on a variety of factors, including without limitation the ability of the selected phages, in combination, to successfully kill the targeted bacteria, the degree of cross-reactivity of the individual phages with the same part of the bacterial targets, the ability of the combined phages to satisfy regulatory requirements, our ability to manufacture sufficient quantities of the phages, intellectual property rights of third parties, and other factors. While we have selected an initial formulation of AB-SA01 for the treatment of *S. aureus* infections, there can be no assurance that this will be the final formulation of AB-SA01 for commercialization. In addition, we have initiated final phage selection for AB-PA01, our *P. aeruginosa* product. AB-CD01, which is our *C. difficile* product, is at an earlier stage. If we are unable to complete formulation development of our product candidates in the time frame that we have anticipated, then our product development timelines, and the regulatory approval of our product candidates, could be delayed.

Our product candidates must undergo rigorous clinical testing, such clinical testing may fail to demonstrate safety and efficacy and any of our product candidates could cause undesirable side effects, which would substantially delay or prevent regulatory approval or commercialization.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new drug candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete.

We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- our product candidates may have unintended or undesirable effects on patients that may delay or preclude regulatory approval of our product candidates or limit their commercial use, if approved.

Results from preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not be predictive of the results of later stage human clinical trials.

Preclinical studies, including studies of our product candidates in animal disease models, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of prototype phage products in the treatment of bacterial infections, such as *P. aeruginosa* and *S. aureus,* may not predict the ability of these products to treat similar infections in humans. Our phage technology may be found not to be efficacious in treating bacterial infections alone or in combination with other agents, when studied in human clinical trials.

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from early stage clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials and most product candidates that commence clinical trials are never approved for commercial sale.

We must continue to develop manufacturing processes for our product candidates and any delay in or our inability to do so would result in delays in our clinical trials.

We are developing novel manufacturing processes for our product candidates at our facility in Ljubljana, Slovenia. The manufacturing processes for our product candidates, and the scale up of such processes for clinical trials, is novel, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. Any delay in the development or scale up of these manufacturing processes could delay the start of clinical trials and harm our business. Our facility in Slovenia must also undergo ongoing inspections by JAZMP, the Slovenian agency that regulates and supervises pharmaceutical products in Slovenia, for compliance with their and the European Medicines Agency's, or EMA's, current good manufacturing practice regulations, or cGMP regulations, before the respective product candidates can be approved for use in clinical trials or commercialization. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate.

Our manufacturing facility will be subject to ongoing periodic inspection by the European regulatory authorities, including JAZMP, and the FDA for compliance with European and FDA cGMP regulations. Compliance with these regulations and standards is complex and costly, and there can be no assurance that we will be able to comply. Any failure to comply with applicable regulations could result in sanctions being imposed (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

We may conduct clinical trials for our products or product candidates outside the United States and the FDA may not accept data from such trials.

We are currently conducting an investigator-sponsored clinical trial of AB-SA01 at the University of Adelaide in Australia for chronic rhinosinusitis, and may seek to conduct one or more other clinical trials in the future outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which

would be costly and time consuming and delay aspects of our business plan.

We may need to license additional intellectual property rights.

The development and commercialization of phage-based antibacterial agents may require us to obtain rights to intellectual property from third parties. For example, pursuant to our Collaborative Research and Development Agreement with the United States Army Medical Research and Materiel Command and the Walter Reed Army Institute of Research, we are currently focusing on developing bacteriophage therapeutics to treat *S. aureus* infections. To the extent the intellectual property is generated from the United States Army Medical Research and Materiel Command or Walter Reed Army Institute of Research that is used in a commercial product, we may be obligated to make payments such as royalties, licensing fees and milestone payments. We may also determine that it is necessary or advisable to license other intellectual property from third parties. There can be no assurance that such intellectual property rights would be available on commercially reasonable terms, if at all.

We are conducting an investigator-sponsored clinical trial of AB-SA01 at the University of Adelaide. To the extent that intellectual property is generated as a result of the study that is used in a commercial product, we may be obligated to make payments, such as royalties, licensing fees, and milestone payments. There can be no assurance that such intellectual property rights would be available on commercially reasonable terms, if at all.

We are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates.

Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. There can be no assurance that our manufacturing facilities will satisfy the requirements of the FDA or comparable foreign authorities. We require the approval of the relevant regulatory authorities before we may commence commercial sales of our product candidates in a given market. The regulatory approval process is expensive and time-consuming, and the timing of receipt of regulatory approval is difficult to predict. Our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability.

Changes in regulatory approval policies during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, or changes in regulatory review practices for a submitted product application may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval.

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

A variety of risks associated with our international operations could materially adversely affect our business.

In addition to our U.S. operations, we have operations and subsidiaries in the United Kingdom, Australia and Slovenia. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for the development, manufacture and, if approved, commercialization of our product candidates;
- difficulties in staffing and managing foreign operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

We do not have a sales force and do not currently have plans to develop one.

The commercial success of any of our product candidates will depend upon the strength of sales and marketing efforts for them. We do not have a sales force and have no experience in sales, marketing or distribution. To successfully commercialize our product candidates, we will need to develop such a capability ourselves or seek assistance from a third party with a large distribution system and a large direct sales force. We may be unable to put such a plan in place. In addition, if we arrange for others to market and sell our products, our revenues will depend upon the efforts of those parties. Such arrangements may not succeed. Even if one or more of our product candidates is approved for marketing, if we fail to establish adequate sales, marketing and distribution capabilities, independently or with others, our business will be materially harmed.

Our success depends in part on attracting, retaining and motivating our personnel.*

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. As of November 3, 2016, we had 32 employees. Our success will depend on our ability to retain and motivate personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We also face competition from other more well-funded and well-established businesses and we may also be viewed as a riskier choice from a job stability perspective due to our relative newer status than longer existing biotech and pharmaceutical companies. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

We must manage a geographically dispersed organization.*

While we are a small company, we currently have operations in the United States, Australia and Slovenia. In the future, we may also locate facilities in other locations based on proximity to personnel with the expertise needed to research, develop and manufacture phage-based therapeutics, costs of operations or other factors. Managing our organization across multiple locations and multiple time zones may reduce our efficiency, increase our expenses and increase the risk of operational difficulties in the execution of our plans.

Risks Related to Our Reliance on Third Parties

We rely on third parties for aspects of product development.

We rely on third parties such as the University of Leicester and the U.S. Army for certain aspects of product development. We are working with the University of Leicester for research and development of product candidates to treat *C. difficile* infections. We are working with the U.S. Army for research and development of product candidates to treat *S. aureus* infections. Because we rely on third parties to conduct these activities, we have less control over the success of these programs than we would if we were conducting them on our own. Factors beyond our control that could impact the success of these programs include the amount of resources devoted to the programs by the applicable third party, the staffing of those projects by third-party personnel, and the amount of time such personnel devote to our programs compared to other programs. Failure of our third-party collaborators to successfully complete the projects that we are working on with them could result in delays in product development and the need to expend additional resources, increasing our expenses beyond current expectations.

We will rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We expect to use third parties, such as clinical research organizations or the U.S. Army, to assist in conducting our clinical trials. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to submit Biologics License Applications, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

Risks Related to Our Intellectual Property

We are dependent on patents and proprietary technology. If we fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer.

Our commercial success will depend in part on our ability to obtain and maintain patent protection sufficient to prevent others from marketing our product candidates, as well as to defend and enforce these patents against infringement and to operate without infringing the proprietary rights of others. Protection of our product candidates from unauthorized use by third parties will depend on having valid and enforceable patents cover our product candidates or their manufacture or use, or having effective trade secret protection. If our patent applications do not result in issued patents, or if our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein. We have a limited number of patents and pending patent applications.

The patent positions of biotechnology companies can be uncertain and involve complex legal and factual questions. This is due to inconsistent application of policy and changes in policy relating to examination and enforcement of biotechnology patents to date on a global scale. The laws of some countries may not protect intellectual property rights to the same extent as the laws of countries having well-established patent systems, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Also, changes in either patent laws or in interpretations of patent laws may diminish the value of our intellectual property. We are not able to guarantee that all of our patent applications will result in the issuance of patents and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we may license from others.

Central provisions of The Leahy-Smith America Invents Act, or the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the United States PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the United States PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, United States PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. The United States Supreme Court is currently reviewing whether it is proper for the United States PTO to give claims their broadest reasonable meaning in post-issuance proceedings. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger's burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the United States PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the United States PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the United States PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not be the first to file patent applications for our inventions;
- others may independently develop similar or alternative product candidates to any of our product candidates that fall outside the scope of our patents;
- our pending patent applications may not result in issued patents;
- our issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- others may design around our patent claims to produce competitive products that fall outside the scope of our patents;
- we may not develop additional patentable proprietary technologies related to our product candidates; and
- we are dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on our behalf, which control the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

An issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents.

We rely on trade secrets and other forms of non-patent intellectual property protection. If we are unable to protect our trade secrets, other companies may be able to compete more effectively against us.

We rely on trade secrets to protect certain aspects of our technology, including our proprietary processes for manufacturing and purifying bacteriophages. Trade secrets are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secret information is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to or may not protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference proceeding, it will be costly and time-consuming, and an unfavorable outcome in that litigation or interference would have a material adverse effect on our business.

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign patents and patent applications, which are owned by third parties, exist in the general field of anti-infective products or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, which may later result in issued patents that our product candidates may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an interference proceeding.

The biotechnology and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. For so long as our product candidates are in clinical trials, we believe our clinical activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our clinical investigational drug product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. While we attempt to ensure that our active clinical investigational drugs and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights, we cannot be certain they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may be exposed to future litigation based on claims that our product candidates, or the methods we employ to manufacture them, or the uses for which we intend to promote them, infringe the intellectual property rights of others. Our ability to manufacture and commercialize our product candidates may depend on our ability to demonstrate that the manufacturing processes we employ and the use of our product candidates do not infringe third-party patents. If third-party patents were found to cover our product candidates or their use or manufacture, we could be required to pay damages or be enjoined and therefore unable to commercialize our product candidates, unless we obtained a license. A license may not be available to us on acceptable terms, if at all.

Risks Related to Our Industry

If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase. Some companies that are larger and have significantly more resources than we do are aggressively pursuing antibacterial development programs, including traditional therapies and therapies with novel mechanisms of action. In addition, other companies are developing phage-based products for non-therapeutic uses, and may elect to use their expertise in phage development and manufacturing to try to develop products that would compete with ours.

We also face potential competition from academic institutions, government agencies and private and public research institutions engaged in the discovery and development of drugs and therapies. Many of our competitors have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing, sales and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies.

Our competitors may succeed in developing products that are more effective, have fewer side effects and are safer or more affordable than our product candidates, which would render our product candidates less competitive or noncompetitive. These competitors also compete with us to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials, as well as to acquire technologies and technology licenses complementary to our programs or advantageous to our business. Moreover, competitors that are able to achieve patent protection, obtain regulatory approvals and commence commercial sales of their products before we do, and competitors that have already done so, may enjoy a significant competitive advantage.

The Generating Antibiotics Incentives Now Act is intended to provide incentives for the development of new, qualified infectious disease products. These incentives may result in more competition in the market for new antibiotics, and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of products that could be competitive with our product candidates.

There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants;
- decreased demand for our product candidates;
- injury to our reputation;
- litigation costs;
- substantial monetary awards against us; and
- diversion of management or other resources from key aspects of our operations.

If we succeed in marketing products, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, or limitations on the indications, for which they may be used, or suspension or withdrawal of approval.

We have product liability insurance that covers our clinical trials up to a $10.0 million annual per claim and aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is expensive and we may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which would negatively affect our ability to achieve profitability.

Our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the price of the product, both in absolute terms and relative to alternative treatments; and
- sufficient third-party coverage or reimbursement.

If our product candidates receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenues sufficient to attain profitability.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability will be negatively affected.

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing

the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration, or OSHA, state and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA, state governments or federal Environmental Protection Agency, or EPA, may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that could have a material adverse effect on our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations.

Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage.

Risks Related to Our Common Stock

The price of our common stock has been and may continue to be volatile.

The stock markets in general, the markets for biotechnology stocks and, in particular, the stock price of our common stock, have experienced extreme volatility. The market for our common stock is characterized by significant price volatility when compared to the shares of larger, more established companies that trade on a national securities exchange and have large public floats, and we expect that our share price will continue to be more volatile than the shares of such larger, more established companies for the indefinite future. The volatility in our share price is attributable to a number of factors. Our common shares are, compared to the shares of such larger, more established companies, sporadically and thinly traded. As a consequence of this limited liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of shares of our common stock are sold on the market without commensurate demand. We are also a speculative or "risky" investment due to the early stage of our drug development programs and our lack of profits to date, and uncertainty of future market acceptance for our potential products and our ability to continue as a going concern. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a larger, more established company that has a large public float and broader stockholder base. Many of these factors are beyond our control and may decrease the market price of our common stock, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common stock will sustain their current market prices, or as to what effect that the sale of shares or the availability of common stock for sale at any time will have on the prevailing market price.

Price declines in our common stock could also result from general market and economic conditions and a variety of other factors, including:

- adverse results or delays in our clinical trials;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials or the manufacturing processes of our product candidates;
- announcements of technological innovations, patents or new products by our competitors;
- regulatory developments in the United States and foreign countries;
- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;

- our inability, or the perception by investors that we will be unable, to continue to meet all applicable requirements for continued listing of our common stock on the NYSE MKT, and the possible delisting of our common stock;
- sales of our common stock by our executive officers, directors and principal stockholders or sales of substantial amounts of common stock; and
- loss of any of our key scientific or management personnel.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. Any such lawsuit could consume resources and management time and attention, which could adversely affect our business.

We may be required to issue a significant number of additional shares of common stock for no additional consideration to certain of our stockholders.*

We may be required to issue a significant number of additional shares of common stock for no additional consideration to the Holders. Pursuant to the CSIA, we agreed that if in the future we conduct one or more bona fide equity financings in which we sell shares of our common stock or preferred stock at a price of less than $4.05 per share, we will issue to the Holders, for no additional consideration, a number of additional shares of common stock ("Additional Shares") based on a specified formula (such rights of the Holders to receive Additional Shares, the "Additional Issuance Rights"). Specifically, in the event we conduct such a financing, the Holders will be entitled to receive (absent consideration of any applicable restrictions on the number of shares that can be issued in a non-public offering under NYSE MKT rules and interpretations without stockholder approval) in the aggregate a number of Additional Shares equal to (A) the product of (x) 1,037,053 multiplied by (y) a fraction, the numerator of which is $4.05 and the denominator of which is the lowest price per share paid by investors in such dilutive financing (the "Effective Price") less (B) 1,037,053 and all Additional Shares issued previously to the Holders pursuant to the Additional Issuance Rights. The CSIA includes a provision intended to limit our obligation to issue Additional Shares to the extent such Additional Shares would exceed the 20% limit on the number of shares that can be issued without stockholder approval pursuant to Section 713(a) of the NYSE MKT Company Guide.

Pursuant to Section 713(a) of the NYSE MKT Company Guide, stockholder approval is generally required prior to the issuance of common stock or common stock equivalents in connection with a transaction other than a public offering involving the sale, issuance, or potential issuance by the issuer of common stock or common stock equivalents equal to 20% or more of the outstanding shares of common stock as of immediately prior to the transaction for less than the greater of book or market value of the stock. At our 2016 annual meeting of stockholders on June 20, 2016, our stockholders approved the issuance by us of up to 1,037,053 Additional Shares, for purposes of Section 713(a) of the NYSE MKT Company Guide, to the extent required to satisfy the Additional Issuance Rights. On June 3, 2016, we completed a registered public offering of common stock and warrants to purchase common stock at a combined price per share and associated warrant of $2.35. As a result of this offering, we issued to the Holders an aggregate of 750,206 Additional Shares. Under Section 713(a) of the NYSE MKT Company Guide, we are permitted to issue without further stockholder approval up to 286,846 Additional Shares to the Holders if and to the extent required by the terms of the CSIA, and we may become required to issue this full amount to the Holders, or a greater amount, if in the future we sell shares of our common stock in a bona fide equity financing at a price of less than $2.35 per share.

Our inability to comply in full with our obligation under the CSIA to issue shares to the Holders in connection with the closing of a financing that triggers Additional Issuance Rights could have additional adverse consequences, including, without limitation:

- the Holders may bring an action against us for breach of contract, or threaten to bring an action against us, either of which could require us to expend significant time and resources to resolve the matter, and we may not be successful;
- we may need to call a special meeting of our stockholders to seek their approval of the issuance by us to the Holders of the number of shares we become obligated to issue the Holders in connection with the closing of such dilutive financing, less the 286,846 shares we are currently permitted to issue, which would require us to expend time and resources, and our stockholders may not ultimately approve such issuance; and
- we may need to provide other consideration to the Holders to settle potential claims arising from our inability to satisfy our contractual obligations under the CSIA, which could involve:
- cash make-whole payments, which in turn would deplete our cash resources faster than we would otherwise anticipate; and
- other unfavorable terms that could make it difficult for us to raise financing in the future, which would raise further doubts about our ability to continue as a going concern.

The occurrence of any of the foregoing, or even the potential for them to occur, could result in a material decline in our stock price.

Stockholders will incur dilution of their percentage ownership interest in our common stock to the extent we issue Additional Shares to the Holders pursuant to the Additional Issuance Rights. In addition, because the Additional Shares will be issued for no additional consideration, any such issuance would reduce our net tangible book value per share.

Any issuance or potential issuance of Additional Shares could adversely affect our stock price, make it more difficult for us to raise capital on favorable terms, or at all, and have a material adverse effect on our business, results of operations and financial condition.

A significant number of shares of our common stock are subject to issuance upon exercise of outstanding warrants and which upon such exercise may result in dilution to our security holders.*

As of September 30, 2016, we had outstanding warrants to purchase an aggregate of 2,443,479 shares of our common stock at a weighted average exercise price of $5.87 per share, and outstanding options to purchase 736,938 shares of our common stock at a weighted average exercise price of $6.78 per share. The exercise price and/or the number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including certain issuances of securities at a price equal to or less than the then current exercise price, subdivisions and stock splits, stock dividends, combinations, reorganizations, reclassifications, consolidations, mergers or sales of properties and assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. Although we cannot determine when these warrants or options will ultimately be exercised, it is reasonable to assume that such warrants and options will be exercised only if the exercise price is below the market price of our common stock. To the extent any of our outstanding warrants or options are exercised, additional shares of our common stock will be issued that will generally be eligible for resale in the public market (subject to limitations under Rule 144 under the Securities Act for certain of our warrants and with respect to shares held by our affiliates), which will result in dilution to our security holders. The issuance of additional securities could also have an adverse effect on the market price of our common stock.

Our principal stockholders and management beneficially own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval. *

As of September 30, 2016, our executive officers, directors, principal stockholders and their affiliates beneficially owned a significant portion of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to significantly affect or, acting together, control matters requiring stockholder approval, including elections of directors, amendments of our organizational documents, and approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Provisions of Washington law and our current articles of incorporation and bylaws may discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.*

Provisions of Washington law and our current articles of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our articles of incorporation and bylaws; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of stockholders owning 10% or more of our outstanding voting stock from merging or combining with us. These provisions could discourage potential acquisition attempts and could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would without these provisions.

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer may be considered

beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.*

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules of the NYSE MKT. The requirements of these rules and regulations increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and place strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently.

We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud.

In accordance with NYSE MKT rules, we are required to maintain a majority independent board of directors. The various rules and regulations applicable to public companies make it more difficult and more expensive for us to maintain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors' and officers' insurance, our ability to recruit and retain qualified officers and directors will be significantly curtailed.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.*

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have three securities analysts and may never obtain additional research coverage by other securities and industry analysts. If no additional securities or industry analysts commence coverage of our company, the trading price for our stock could be negatively impacted. If we obtain additional

securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

We are an "emerging growth company," as defined under the JOBS Act. For so long as we are an "emerging growth company," we intend to take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.