

AmpliPhi Biosciences Corp  
Form 10-Q  
November 16, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**<sup>X</sup> QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2015

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission file number: 001-37544**

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

**Washington**

(State or other jurisdiction of

incorporation or organization)

**91-1549568**

I.R.S. Employer Identification Number)

**800 East Leigh Street, Suite 209**

**23219**

**Richmond, Virginia**

(Zip Code)

(Address of principal executive offices)

Registrant's telephone number, including area code: **(804) 827-2524**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company 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

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

Yes  No

The number of shares of the Registrant's Public Common Stock outstanding at November 10, 2015 was 5,883,503.



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**AmpliPhi Biosciences Corporation****Consolidated Balance Sheets**

	September 30, 2015 (Unaudited)	December 31, 2014
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 11,737,000	\$ 6,581,000
Accounts receivable	40,000	100,000
Prepaid expenses and other current assets	785,000	339,000
Total current assets	12,562,000	7,020,000
Property and equipment, net	1,162,000	1,220,000
In process research and development	12,446,000	12,446,000
Acquired patents, net	346,000	369,000
Goodwill	7,562,000	7,562,000
Total assets	\$ 34,078,000	\$ 28,617,000
<b>Liabilities, Series B redeemable convertible preferred stock and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable, accrued expenses and other	\$ 1,153,000	\$ 1,167,000
Deferred revenue	247,000	244,000
Accrued severance	491,000	457,000
Dividends payable	368,000	-
Total current liabilities	2,259,000	1,868,000
Series B preferred stock derivative liability	2,127,000	12,320,000
Warrant liability	10,000	5,826,000
Accrued severance	-	98,000
Deferred tax liability	3,078,000	3,078,000
Total liabilities	7,474,000	23,190,000
<b>Series B redeemable convertible preferred stock</b>		
\$0.01 par value, 9,357,935 shares authorized at September 30, 2015 and December 31, 2014, 7,527,853 shares issued and outstanding at September 30, 2015 and 8,671,040 shares issued and outstanding at December 31, 2014 (liquidation preference of \$13,068,000 and \$14,042,000 at September 30, 2015 and December 31, 2014, respectively)	10,941,000	1,990,000
<b>Stockholders' equity</b>		
Common stock, \$0.01 par value, 670,000,000 shares authorized at September 30, 2015 and 445,000,000 shares authorized at December 31, 2014, 5,883,503 shares issued and outstanding at September 30, 2015 and 3,983,182 shares issued and outstanding December 31, 2014	59,000	40,000

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Additional paid-in capital	375,895,000	365,403,000
Accumulated deficit	(360,291,000)	(362,006,000)
Total stockholders' equity	15,663,000	3,437,000
Total liabilities, Series B redeemable convertible preferred stock and stockholders' equity	\$ 34,078,000	\$ 28,617,000

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,	
	2015	2014	2015	2014
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue	\$ 143,000	\$ 103,000	\$ 347,000	\$ 308,000
Operating expenses				
Research and development	728,000	1,793,000	2,777,000	4,692,000
General and administrative	1,554,000	1,701,000	4,568,000	5,289,000
Severance expense	289,000	1,840,000	289,000	1,840,000
Total operating expenses	2,571,000	5,334,000	7,634,000	11,821,000
Loss from operations	(2,428,000 )	(5,231,000 )	(7,287,000 )	(11,513,000 )
Other income (expense)				
Change in fair value of warrant liability	693,000	7,079,000	607,000	9,245,000
Change in fair value of Series B preferred stock derivative liability	7,045,000	19,359,000	8,697,000	26,041,000
Other income (expense)	129,000	-	(302,000 )	-
Total other income	7,867,000	26,438,000	9,002,000	35,286,000
Net income	5,439,000	21,207,000	1,715,000	23,773,000
Accretion of Series B redeemable convertible preferred stock	(7,163,000 )	(323,000 )	(9,329,000 )	(955,000 )
Net (loss) income attributable to common stockholders	\$ (1,724,000 )	\$ 20,884,000	\$ (7,614,000 )	\$ 22,818,000
Per share information:				
Net (loss) income per share of common stock - basic	\$ (0.30 )	\$ 5.58	\$ (1.45 )	\$ 6.19
Weighted average number of shares of common stock outstanding - basic	5,813,063	3,743,182	5,247,508	3,688,903
Net (loss) income per share of common stock - diluted	\$ (0.30 )	\$ 3.30	\$ (1.45 )	\$ 3.53
Weighted average number of shares of common stock outstanding - diluted	5,813,063	6,319,802	5,247,508	6,472,093

See accompanying condensed notes to consolidated financial statements.

## AmpliPhi Biosciences Corporation

## Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Redeemable Convertible Preferred Stock		Stockholders' Equity (Deficit)				Total Stockholders' Equity (Deficit)
	Series B		Common Stock		Additional Paid-	Accumulated	
	Shares	Amount	Shares	Amount	in Capital	Deficit	
Balances, December 31, 2013	8,859,978	\$707,000	3,650,711	\$36,000	\$362,454,000	\$(385,115,000)	\$(22,625,000 )
Net income	-	-	-	-	-	23,109,000	23,109,000
Accretion of dividends on Series B redeemable convertible preferred stock	-	1,285,000	-	-	(1,285,000 )	-	(1,285,000 )
Warrants exercised	-	-	54,683	1,000	1,594,000	-	1,595,000
Conversion of Series B redeemable convertible preferred stock to common stock	(188,938 )	(2,000 )	37,788	1,000	706,000	-	707,000
Stock-based compensation	-	-	-	-	775,000	-	775,000
Stock-based compensation - severance	-	-	-	-	1,161,000	-	1,161,000
Shares released from escrow	-	-	240,000	2,000	(2,000 )	-	-
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 income	-	-	-	-	-	1,715,000	1,715,000
Accretion of dividends on Series B redeemable	-	992,000	-	-	(992,000 )	-	(992,000 )



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convertible preferred stock Amount reclassified to Series B redeemable convertible stock to accrete to its redemption value	-	8,337,000	-	-	(8,337,000	)	-	(8,337,000	)
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 fair value of warrants issued	-	-	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 to amendment of warrants	-	-	-	-	5,462,000	-	-	5,462,000	
Warrants reclassified from liabilities to equity due to increase in authorized shares	-	-	-	-	3,280,000	-	-	3,280,000	
Exercise of common stock options and other	-	-	39,281	-	-	-	-	-	
Stock-based compensation	-	-	-	-	249,000	-	-	249,000	
Stock-based compensation - severance	-	-	-	-	4,000	-	-	4,000	
Balances, September 30, 2015	7,527,853	\$ 10,941,000	5,883,503	\$ 59,000	\$ 375,895,000	\$(360,291,000)		\$ 15,663,000	

(Unaudited)

See accompanying condensed notes to consolidated financial statements.

**AmpliPhi Biosciences Corporation****Consolidated Statement of Cash Flows**

	Nine Months Ended September 30,	
	2015	2014
	(Unaudited)	(Unaudited)
Operating activities:		
Net income	\$ 1,715,000	\$ 23,773,000
Adjustments required to reconcile net income to net cash used in operating activities:		
Change in fair value of warrant liability	(607,000 )	(9,245,000 )
Change in fair value of Series B preferred stock derivative liability	(8,697,000 )	(26,041,000 )
Gain on re-valuation of liquidated damages liability	(120,000 )	-
Warrants issued to placement agents	213,000	-
Amortization of patents	23,000	23,000
Depreciation	217,000	59,000
Stock-based compensation	249,000	714,000
Stock-based compensation - severance	4,000	1,161,000
Changes in operating assets and liabilities:		
Accounts receivable	60,000	(19,000 )
Accounts payable, accrued expenses, deferred revenue and other	(11,000 )	(305,000 )
Accrued severance	(64,000 )	659,000
Prepaid expenses and other current assets	(446,000 )	(151,000 )
Net cash used in operating activities	(7,464,000 )	(9,372,000 )
Investing activities:		
Purchases of property and equipment	(160,000 )	(1,197,000 )
Net cash used in investing activities	(160,000 )	(1,197,000 )
Financing activities:		
Proceeds from warrant exercises	396,000	-
Proceeds from issuance of common stock, net	12,384,000	-
Net cash provided by financing activities	12,780,000	-
Net increase (decrease) in cash and cash equivalents	5,156,000	(10,569,000 )
Cash and cash equivalents, beginning of period	6,581,000	20,355,000
Cash and cash equivalents, end of period	\$ 11,737,000	\$ 9,786,000
Supplemental schedule of non-cash financing activities:		
Accretion of Series B redeemable convertible preferred stock	\$ 9,329,000	\$ 955,000
Fair value of warrant liability upon issuance	4,210,000	-

See accompanying condensed notes to consolidated financial statements.

**AmpliPhi Biosciences Corporation**

**Condensed Notes to Consolidated Financial Statements**

**September 30, 2015**

**(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.

As a development stage company, it has incurred net losses since its inception, has negative operating cash flows, and had an accumulated deficit of \$360.3 million and \$362.0 million as of September 30, 2015 and December 31, 2014, respectively. The Company completed a \$13.0 million private placement of its common stock in March 2015, which provided net proceeds of approximately \$12.4 million after commissions to placement agents. In the opinion of management, the Company has resources sufficient to fund its planned operations through the third quarter of 2016. This estimate is based on the Company’s current product development plans, projected staffing expenses, working capital requirements, and capital expenditure plans.

**2. Significant Accounting Policies**

The Company’s significant accounting policies are described in Note 2 to the Consolidated Financial Statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014. 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, 2014 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (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 account 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, 2015 and the results of its operations for the three and nine months ended September 30, 2015 and 2014. 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 preferred stock derivatives, the fair value of liability-classified warrants, the valuation of long-lived assets, including in-process research and development (IPR&D), patents and goodwill, accrued expenses and the recoverability of the Company's net deferred tax assets and related valuation allowance.



### ***Cash and Cash Equivalents***

Cash and cash equivalents consist primarily of deposits with commercial banks and financial institutions. Cash equivalents include short-term investments that have a maturity at the time of purchase of three months or less, are readily convertible into cash and have an insignificant level of valuation risk attributable to potential changes in interest rates. Cash equivalents are recorded at cost plus accrued interest, which approximates fair market value.

### ***Accounts Receivable***

Accounts receivable amounts are stated at their face amounts less any allowance. Provisions for doubtful accounts are estimated based on an assessment of the probable collection from specific customer accounts and other known factors. As of September 30, 2015 and December 31, 2014, management determined no allowance for doubtful accounts was required.

### ***In-Process Research & Development and Goodwill***

In-process research & development (IPR&D) assets represent capitalized incomplete research projects that the Company acquired through business combinations. Such assets are initially measured at their acquisition date fair values. The fair value of the research projects is recorded as intangible assets on the consolidated balance sheet rather than expensed regardless of whether these assets have an alternative future use. The amounts capitalized are being accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, the Company will make a determination as to the then remaining useful life of the intangible asset and begin amortization.

Costs of investments in purchased companies in excess of the underlying fair value of net assets at the date of acquisition are recorded as goodwill and assessed annually for impairment. If considered impaired, goodwill will be written down to fair value and a corresponding impairment loss recognized.

We review the carrying value of IPR&D and goodwill for potential impairment on an annual basis and at any time that events or business conditions indicate that it may be impaired. As permitted under Accounting Standards Codification Topic 350 (ASC 350), through December 31, 2014, we have elected to base our assessment of potential impairment on qualitative factors. Based on our assessment, IPR&D and goodwill were not impaired as of December 31, 2014.

### ***Warrant and Preferred Shares Conversion Feature Liability***

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

### ***Foreign Currency Translations and Transactions***

The functional currency of our wholly-owned subsidiaries is the U.S. dollar.

### ***Other Comprehensive Income (Loss)***

The Company recorded no comprehensive income other than net income for the periods reported.

### ***Recent Accounting Pronouncements***

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 financial statements.

## **3. 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 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 and embedded derivatives related to the Company's redeemable convertible preferred stock. 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 for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
September 30, 2015				
Liabilities				
Series B preferred stock derivative liability	\$ -	\$ -	\$ 2,127,000	\$2,127,000
Warrant liability	-	-	10,000	10,000
Total liabilities	\$ -	\$ -	\$ 2,137,000	\$2,137,000
December 31, 2014				
Liabilities				

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Series B preferred stock derivative liability	\$	-	\$	-	\$ 12,320,000	\$ 12,320,000
Warrant liability		-		-	5,826,000	5,826,000
Total liabilities	\$	-	\$	-	\$ 18,146,000	\$ 18,146,000

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, 2015 and the year ended December 31, 2014.

The following table sets forth a summary of changes in the fair value of the Company's Series B redeemable convertible preferred stock derivative and warrant liability, 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	Series B Preferred Stock Derivative Liability
Balance, December 31, 2014	\$5,826,000	\$ 12,320,000
Issuances	4,210,000	-
Exercises	(676,000 )	-
Conversions to common stock	-	(1,496,000 )
Warrants reclassified from liabilities to equity due to amendment of warrants	(5,462,000)	-
Warrants reclassified from liabilities to equity due to increase in authorized shares	(3,281,000)	-
Changes in estimated fair value	(607,000 )	(8,697,000 )
Balance, September 30, 2015	\$ 10,000	\$ 2,127,000

The fair value of the warrants on the date of issuance and on each re-measurement date for warrants 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 following assumptions were used at September 30, 2015 and December 31, 2014:

	September 30, 2015		December 31, 2014							
	Series (1)		Series (1)							
	2011		2011	June 2013	July 2013	December 2013				
Volatility	112	%	155	%	155	%	155	%	151	%
Expected term (years)	1.23		1.98		3.49		3.54		3.98	
Risk-free interest rate	0.40	%	0.67	%	1.23	%	1.25	%	1.37	%
Dividend yield	0.00	%	0.00	%	0.00	%	0.00	%	0.00	%
Exercise price	\$ 23.00		\$23.00		\$7.00		\$7.00		\$ 12.50	
Common stock closing price	\$ 3.95		\$10.50		\$10.50		\$10.50		\$ 10.50	

(1) See *Note 6 – Warrants* below for further description of the respective series of warrants.

The warrant liability is recorded on the accompanying consolidated balance sheets and is marked-to-market at each reporting period, with the change in fair value recorded as a component of change in fair value of warrant liability on the Company's statements of operations.

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 preferred stock, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the Series B preferred conversion liability is considered a Level 3 measurement. The following assumptions were used at September 30, 2015 and December 31, 2014:

	September 30, 2015		December 31, 2014	
Volatility	102	%	91	%
Expected term (years)	1.63		1.25	

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Risk-free interest rate	0.08	%	0.36	%
Common stock dividend yield	0.00	%	0.00	%
Minimum non-diluting issuance price	\$ 7.00		\$ 7.00	
Common stock closing price	\$ 3.95		\$ 10.50	

The Series B preferred stock derivative liability is recorded on the accompanying consolidated balance sheet and is marked-to-market each reporting period, with the change in fair value recorded as a component of change in fair value of Series B preferred stock derivative liability on the Company's statements of operations.

#### 4. Net (Loss) Income per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Basic and diluted net (loss) income per common share calculation:				
Net income	\$5,439,000	\$21,207,000	\$1,715,000	\$23,773,000
Accretion of Series B redeemable convertible preferred stock	(7,163,000)	(323,000 )	(9,329,000)	(955,000 )
Net (loss) income attributable to common stockholders	\$(1,724,000)	\$20,884,000	\$(7,614,000)	\$22,818,000
Weighted average common shares outstanding - basic	5,813,063	3,743,182	5,247,508	3,688,903
Net income (loss) per share of common stock - basic	\$(0.30 )	\$5.58	\$(1.45 )	\$6.19
Weighted average common shares outstanding - diluted	5,813,063	6,319,802	5,247,508	6,472,093
Net income (loss) per share of common stock - diluted	\$(0.30 )	\$3.30	\$(1.45 )	\$3.53

The following outstanding securities at September 30, 2015 and 2014 have been excluded from the computation of diluted weighted shares outstanding for the nine months ended September 30, 2015 and 2014, as they would have been anti-dilutive:

	September 30, 2015	September 30, 2014
Options	631,126	15,280
Warrants	1,209,681	-
Series B redeemable convertible preferred stock as converted	1,505,571	-
Escrow	-	240,000
Total	3,346,378	255,280

#### 5. 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. Each Series B share is convertible into 0.20 shares of common stock and is entitled to the number of votes equal to the number of shares of common stock into which such Series B share may be converted. These Series B shares may be converted to common stock by the holder of the shares at any time. The Series B shares shall be automatically converted into common stock upon the closing of an underwritten initial public offering by the Company occurring after June 13, 2013, with aggregate proceeds to the Company of at least \$7.0 million and a price per share to the public of at least the Series B stated value of \$1.40 per share upon the closing of which the shares of common stock of the Company are listed for trading on a major national stock exchange.

Holders of the Series B shares are entitled to receive cumulative, cash dividends at the rate of 10% of the Series B stated value. Such dividends accrue from day-to-day commencing on the original issue date, whether or not earned or declared by the Board of Directors, and are compounded annually. No dividends have been declared or paid through September 30, 2015.

At any time on or after June 26, 2018, the holders of at least two-thirds of the outstanding Series B shares may require the Company to redeem all 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 are 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 the Company merges with or is acquired by another entity.

In connection with the private placement of Series B, the Company recorded a liability for an embedded derivative that required bifurcation under the applicable accounting guidance. The embedded derivative includes 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 non-diluting issuance price of \$7.00 per share.

The following table summarizes the conversions of Series B shares to common stock pursuant to Series B shareholder elections during the nine months ended September 30, 2015:

Conversion Date	Series B Shares Converted	Common Stock Issued	Amount Reclassified from Liability into Stockholders' Equity <sup>(1)</sup>
April 8, 2015	107,100	21,420	\$ 219,000
May 4, 2015	23,587	4,717	36,000
May 11, 2015	250,000	50,000	381,000
July 16, 2015	262,500	52,500	318,000
August 13, 2015	500,000	100,000	542,000
Totals	1,143,187	228,637	\$ 1,496,000

(1) Not inclusive of liabilities for dividends payable upon conversion of these shares.

The Company re-measured the fair value of the derivative feature and recorded a gain of \$7,045,000 for the quarter ended September 30, 2015 to adjust the liability associated with the conversion feature to its estimated fair value of \$2,127,000 as of September 30, 2015. For the nine months ended September 30, 2015, the Company recorded a gain of \$8,697,000 related to the change in fair value of the derivative feature.

At September 30, 2015, the Company reclassified \$8,337,000 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, an increase of \$6,845,000 from the \$1,492,000 recorded at June 30, 2015, which was attributable to the reduction in the fair market value of the Series B stock derivative liability at September 30, 2015 as compared to June 30, 2015.

At September 30, 2015, the Company recorded dividends payable of \$368,000 to former holders of preferred stock, which are classified as current liabilities on the Company's Balance Sheet at that date.

## 6. Warrants

In connection with the March 16, 2015 private placement of 1,575,758 shares of the Company's common stock at a price per share of \$8.25, the Company issued warrants (Series March 2015) 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. In addition, the Company issued warrants to purchase an aggregate of 94,548 shares of common stock at an exercise price of \$10.75 per share to the placement agents. These warrants expire in March 2020 and provided for a contingent cash payment of \$2.5 million in liquidated damages to the holders of the warrants in the event the Company failed to either (i) increase the number of shares of common stock the Company is authorized to issue or (ii) effect a reverse split of the common stock, in either event sufficient to permit the exercise in full of the Warrants in accordance with their terms. Due to these provisions, the Company accounted for these warrants as liability instruments prior to the third quarter of 2015. The Company measured the fair value of these warrants on March 16, 2015 and recorded an initial warrant liability of \$4,210,000, of which \$3,396,000 represented the initial fair value of the warrants issued to investors and \$814,000 as the initial fair value of the warrants issued to the placement agents. The Company recorded other expenses of \$213,000 for the nine months ended September 30, 2015 representing a portion of the initial fair value of warrants issued to the placement agents attributable to the initial fair value of the warrants issued.

In connection with the December 2013 private placement of 1,440,140 shares of the Company's common stock at a price per share of \$12.50, the Company issued warrants (Series December 2013) to purchase an aggregate of 86,408 shares of common stock at an exercise price of \$12.50 per share to the placement agents. These warrants, which expire December 2018, contain specified anti-dilution adjustment provisions for certain financing transactions involving the issuance of securities below a specified price and contain net settlement provisions. Due to these provisions, the Company accounted for these warrants as liability instruments. As a result of the March 16, 2015 private placement of common stock at a price of \$8.25 per share, the anti-dilution adjustment provisions of these warrants resulted in an adjustment to their exercise price to \$8.25 as of March 16, 2015.

In connection with the private placement of Series B, which occurred through two closings on June 26, 2013 and July 15, 2013, the Company issued warrants (Series June 2013 and Series July 2013, respectively) to purchase an aggregate of 600,804 shares of common stock at an exercise price of \$7.00 per share. These warrants, which expire in June 2018 and in July 2018, respectively, contain anti-dilution adjustment provisions and contain net settlement provisions. Due to these provisions, the Company accounts for these warrants as liability instruments. The Company measured the fair value of these warrants on June 26, 2013 and July 15, 2013 and recorded initial warrant liabilities of \$4,285,000 and \$674,000, respectively, as part of the private placement proceeds and expensed \$759,000 for warrants issued to the placement agent.

In January 2011, we completed the acquisition of Biocontrol Limited, an antimicrobial biotechnology company based in the United Kingdom, with the goal of developing their phage therapy programs using funding from the sale of our legacy gene therapy assets. On December 22, 2011, in connection with our acquisition of Biocontrol, the Company issued warrants (Series 2011) to purchase up to 27,103 shares of its common stock. These warrants expire in December 2016 and are exercisable at a price of \$23.00 per share. As the terms of these warrants require that they be settled in registered shares of common stock, the Company accounts for these warrants as liability instruments.

The Company estimates the fair values of all warrants accounted for as liability instruments using a Monte Carlo valuation model.



From February through May 2013, in connection with the issuance of new convertible promissory notes, the Company issued warrants (Series 2013 Convertible Notes Warrants) to purchase up to 140,608 shares of its common stock. These warrants expire February through May 2018 and are exercisable at a price of \$7.00 per share. The Company classifies these warrants as equity instruments.

On April 1, 2015, 52,120 warrants, issued on June 26, 2013, were exercised, resulting in the issuance of 52,120 shares of common stock and \$630,000 being reclassified from the warrant liability account and into stockholders' equity, based on the fair value of the warrants on the exercise date. On April 29, 2015, 4,524 warrants, issued on June 26, 2013, were exercised, resulting in the issuance of 4,524 shares of common stock and \$46,000 was reclassified from the warrant liability account and into stockholders' equity, based on the fair value of the warrants on the exercise date.

On May 8, 2015, the Company, upon approval of more than two-thirds of the holders of the 2013 warrants issued on June 26, 2013, July 15, 2013 and December 23, 2013, amended these warrants to remove certain anti-dilution adjustment provisions. As a result of this amendment, all outstanding warrants from those issuance dates were reclassified as equity instruments resulting in the reclassification of \$5,462,000 from the warrant liability to stockholders' equity, reflecting the fair value of these warrants on the amendment date.

On August 3, 2015, the shareholders of the Company approved a 1-for-50 reverse stock split of the Company's common stock and increased the number of authorized shares of common stock to 670,000,000. As a result, the warrants issued in conjunction with the March 2015 private placement of common stock were reclassified from liability instruments to equity instruments. Accordingly, \$3,281,000 was reclassified from warrant liability to stockholders' equity, reflecting the fair value of these warrants on the effective date of the reverse split, and the accrued fair value of liquidated damages in the amount of \$120,000 were also reclassified to stockholders' equity.

The Company re-measured the fair value of the warrant liability and recorded a gain of \$693,000 for the quarter ended September 30, 2015, reflecting a decrease in the liability associated with the warrants at their estimated fair value, which totaled \$10,000 as of September 30, 2015. For the nine months ended September 30, 2015 the Company recorded a gain of \$607,000 related to the change in fair value of the warrants for that period.

All exercise prices and share amounts of warrants are after giving consideration to the 1-for-50 reverse split of the Company's common stock which was effective August 7, 2015.

The following table provides a summary of warrants outstanding, issued or exercised for the nine months ended September 30, 2015. Also included is the average exercise price per share and the aggregate proceeds to the Company if exercised as of September 30, 2015.

Series	June 2013 and July 2013										
	March 2015	Series B Warrants		December 2013	2013 Convertible Notes			2014		Totals	
	Shares	Exercise Price	Shares	Exercise Price	Shares	Exercise Price	Shares	Exercise Price	Shares	Exercise Price	Shares
Balance, December 31, 2014	-	\$-	523,705	\$7.00	86,410	\$12.50	140,611	\$7.00	27,104	\$23.00	777,831
Issuances	488,496	10.75	-	-	-	-	-	-	-	-	488,496
Exercises	-	-	(56,645)	7.00	-	-	-	-	-	-	(56,645)
Balance, September 30, 2015	488,496	\$10.75	467,060	\$7.00	86,410	\$12.50	140,611	\$7.00	27,104	\$23.00	1,209,601
Aggregate proceeds if exercised	\$5,251,332		\$3,269,420		\$1,080,125		\$984,277		\$623,392		\$11,975,146

## 7. Stockholders' Equity (Deficit)

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 393,948 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 94,548 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 \$3,998,000 was treated as a reduction of additional paid-in-capital. In addition, \$218,000 of the fees paid to its placement agent were expensed as other expenses in the nine months ended September 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.

## 8. Stock-Based Compensation

The Company's 2013 Stock Incentive Plan (Stock Incentive Plan) provides for the issuance of long-term incentive awards, or awards, in the form of non-qualified and incentive stock options, stock appreciation rights, stock grants and restricted stock units. 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. 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 become exercisable over a four-year period following the date of grant. Every non-employee member of the Company's Board of Directors may also receive an annual non-qualified stock option or restricted stock unit grant. Upon the exercise of stock options, the Company issues the resulting shares from shares reserved for issuance under the Stock Incentive Plan.

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 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Research and development	\$ 29,000	\$ 38,000	\$ 88,000	\$ 116,000
General and administrative	116,000	209,000	161,000	598,000
Severance charge	4,000	1,161,000	4,000	1,161,000
Total stock-based compensation	\$ 149,000	\$ 1,408,000	\$ 253,000	\$ 1,875,000

The following table summarizes stock option activity for the nine months ended September 30, 2015:

	Options Outstanding				
	Shares Available For Grant	Shares	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Intrinsic Value
Balance, December 31, 2014	785,000	440,695	\$ 9.37	8.18	\$ 640,837

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Increase in authorized shares	520,000				
Granted	(547,181)	547,181	8.72	-	-
Exercised	-	(214,815)	8.00	-	(383,994)
Forfeited	4,812	(4,812)	13.64	-	-
Expired	-	(137,123)	10.19	-	-
Balance, September 30, 2015	762,631	631,126	\$ 9.06	9.38	\$256,843
Vested or expected to vest at September 30, 2015		499,995	\$ 9.05	9.26	\$-
Exercisable at September 30, 2015		66,205	\$ 11.45	5.98	\$-

The intrinsic value of options exercisable as of September 30, 2015 was \$0.0 million, based on the Company's closing stock price of \$3.95 per share and a weighted average exercise price of \$11.45 per share.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of standard stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company's common stock, assumptions related to the expected price volatility of the Company's common stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's common stock. The Company uses Monte Carlo valuation models to estimate the fair value of certain stock options with market-based vesting requirements. This method of option pricing involves the use of inputs such as the market value of the Company's common stock, stock price volatility, the period during which the options will be outstanding, the rate of return on risk-free investments, expected dividend yield for the Company's stock, and certain estimates of future value of the Company's common stock.

During the third quarter of 2015, the Company issued 547,181 common stock options to its executives and board members with an average exercise price \$8.72 per share. Included in this amount were 399,716 stock options, with an exercise price of \$9.45, to its Chief Executive Officer, pursuant to his employment agreement dated April 24, 2015.

As of September 30, 2015, there was \$4.4 million of total unrecognized compensation expense related to unvested stock options that will be recognized over the weighted average remaining period of 1.98 years.

### ***Shares Reserved For Further Issuance***

As of September 30, 2015, the Company had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Stock options outstanding	631,126
Available for future grants under the Stock Incentive Plan	762,631
Warrants	1,209,681
Total shares reserved	2,603,438

## **9. 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, 2015, the Company recorded no payments under the Collaborative Research and Development Agreement. During the three and nine months ended September 30, 2014, the Company paid Walter Reed Army Institute of Research \$0 and \$202,000, respectively, for services provided under the Collaborative Research and Development Agreement.

In March 2013, the Company entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation. This agreement allows 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 is 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 is 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, 2015. 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 totaling \$40,000 and \$75,000, respectively. During the three and nine months ended September 30, 2014, the Company recorded \$304,000 and \$843,000, respectively, in expenses under the Exclusive Channel Collaboration Agreement, with cash payments totaling \$214,000 and \$730,000, respectively.

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. In October 2014, the Company renewed this collaboration, effective as of November 9, 2014. This agreement expired November 12, 2015. The Company expects the agreement to be renewed. During the three and nine months ended September 30, 2015, the Company paid and expensed amounts to the University of Leicester under the Leicester Development Agreements in the amount of \$55,000 and \$220,000, respectively. During the three and nine months ended September 30, 2014, the Company paid and expensed amounts to the University of Leicester under the Leicester Development Agreements in the amount of \$0 and \$166,000, respectively. The Company paid and expensed amounts to the University of Glasgow under the Leicester Development Agreements of \$0 and \$61,000 for the three and nine months ended September 30, 2015 respectively. The Company paid and expensed amounts to the University of Glasgow under the Leicester Development Agreements of \$61,000 and \$184,000 for the three and nine months ended September 30, 2014, 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 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 shall 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.

## 10. Severance Charge

On September 15, 2014, by mutual agreement of the Board of Directors (the “Board”) of the Company and Philip J. Young, Mr. Young stepped down from his role as President and Chief Executive Officer of the Company, effective September 15, 2014. In accordance with Mr. Young’s employment agreements, the Company recorded a severance charge in 2014 of \$1,864,000 related to severance-period compensation and benefits and stock-based compensation expense related to the accelerated vesting of stock options. In the third quarter of 2015, the Company recorded an additional severance charge of \$289,000 related to the departure of an executive, which included severance period compensation and benefits and stock-based compensation related to the accelerated vesting of stock options.

The severance accrual as of December 31, 2014 and September 30, 2015 is as follows:

Accrued severance, December 31, 2014	\$555,000
Cash payments in 2015	(351,000)
Additions in 2015	287,000
Accrued severance, September 30, 2015	\$491,000

## 11. Legal Proceedings

The Company is not involved in any legal proceedings that it expects to have a material adverse effect on its business, financial condition, results of operations and cash flows.

## 12. Subsequent Events

On November 2, 2015, the Company signed a Clinical Trial Agreement with the Adelaide Research & Innovation Pty Ltd on behalf of the University of Adelaide for the conduct of a Phase One Investigator Initiated clinical trial to evaluate the safety and tolerability of AB-SA01 in patients with chronic rhinosinusitis associated with Staphylococcus aureus infection. The study will be conducted at the Queen Elizabeth Hospital Department of Otolaryngology Head and Neck Surgery.

On November 5, 2015, the Company's Board of Directors appointed Vijay Samant as a Class II director of the Company and Paul C. Grint, M.D. as a Class III director of the Company. In connection with their appointments on November 5, 2015, each of Mr. Samant and Dr. Grint was granted, under the Company's 2013 Stock Incentive Plan, a stock option to purchase 16,200 of the Company's common stock at an exercise price per share of \$5.65, which was the closing price of the Company's common stock on the NYSE MKT on the date of grant. Each of the stock options vests as follows: 25% of the shares subject to the option will vest one year following the date of grant, and thereafter the remaining shares will vest in equal monthly installments over the following 36 months. As non-employee directors, each of Mr. Samant and Dr. Grint will also be entitled to receive an annual cash retainer of \$40,000 for his service on the Board.

## **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, 2014 included with our Annual Report filed with the SEC.

Statements contained in this report that are not statements of historical fact are forward-looking statements within the meaning 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 third quarter of 2016, future revenue sources, selling and marketing expenses, general and administrative expenses, clinical trial and other research and development expenses, capital resources, capital expenditures, tax credits and carry-forwards, and additional financings or borrowings. 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**

AmpliPhi Biosciences is a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Our proprietary pipeline is based on the use of bacteriophages, a family of viruses that infect only bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacterial pathogens, including the so-called multi-drug-resistant or “Superbug” strains.

We are combining our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of our collaboration partners in bacteriophage biology, drug engineering, development and manufacturing, to develop second-generation bacteriophage products. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current medicines.

Our lead programs consist of three product candidates: AB-PA01, for the treatment of *P. aeruginosa* lung infections in cystic fibrosis (CF) patients; AB-SA01, for the treatment of *S. aureus* infections, including methicillin-resistant *S. aureus* (MRSA) infections; and AB-CD01, for the treatment of *C. difficile* infections.

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. We have raised approximately \$43.6 million in capital since the shift in our focus to novel phage therapeutics in February 2011 to support our operations, including a \$13 million private placement of common stock in March 2015, which provided us with net proceeds of approximately \$12.4 million after commissions to placement agents.

To date, we have not generated any product revenue and have primarily financed our operations through the sale and issuance of convertible notes and the private placement of our equity securities. As of September 30, 2015, we had a cumulative deficit of \$360.3 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 expect our research and development expenses to increase 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 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 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. We expect that these funds 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 attractive terms, we would be forced to delay, reduce or eliminate our research and development programs.

## **Results of Operations**

### **Comparison of three and nine months ended September 30, 2015 and 2014**

#### ***Revenue***

For the quarters ended September 30, 2015 and 2014, we recognized \$0.1 million in revenue related to sublicensing agreements from our former gene therapy program. For the nine months ended September 30, 2015 and 2014, we recognized \$0.3 million in revenue from these sublicenses.

#### ***Research and Development Expenses***

Research and development expenses for the quarter ended September 30, 2015 totaled \$0.7 million compared to \$1.8 million incurred in the same period of 2014. This decline of \$1.1 million was primarily related to lower non-clinical research spending in 2015 as compared to 2014, the impact of one-time start-up costs in 2014 related to our Slovenia cGMP manufacturing facility, the elimination of certain UK-based personnel, and the benefit from Australian government research grants of \$0.3 million in 2015.

Research and development expenses for the nine months ended September 30, 2015 totaled \$2.8 million compared to \$4.7 million incurred in the same period of 2014. This decline of \$1.9 million was primarily related to lower non-clinical research spending in 2015 as compared to 2014, one-time start-up costs in 2014 related to our Slovenia cGMP manufacturing facility, and Australian government research grants of \$0.3 million in 2015. Partially offsetting these factors were increased costs related to the Slovenian facility being operational for the full nine months ended September 30, 2015.

We anticipate that research and development spending in future periods will increase from levels of the first nine months of 2015 as we initiate non-clinical research studies, hire additional research and development staff, prepare to start clinical trials, and continue our discovery efforts.

#### ***General and Administrative Expenses***

General and administrative expenses for the quarter ended September 30, 2015 were \$1.6 million compared to \$1.7 million for the same period of 2014. The \$0.1 million decrease was primarily attributable to \$0.3 million expensed in the third quarter of 2014 related to payments to certain shareholders as required by the terms of our Series B Preferred Stock Purchase Agreement, which were partially offset by increases in compensation and general corporate expenses.

General and administrative expenses for the nine months ended September 30, 2015 were \$4.6 million compared to \$5.3 million for the same period of 2014. This \$0.7 million decrease was primarily attributable to lower cash and stock compensation expenses related to the departure of the Company's prior Chief Executive Officer in the third quarter of 2014 and \$0.5 million expensed in the same period of 2014 related to payments to certain shareholders as required by the terms of our Series B Preferred Stock Purchase Agreement. Partially offsetting these reductions were payroll costs associated with the appointment of our new Chief Executive Office on May 18, 2015 and higher legal and accounting fees in 2015 as compared to 2014.

#### ***Other Income (Expense)***

We recorded a gain of \$0.7 million for the quarter ended September 30, 2015 related to the change in fair value of our warrant liability, which was primarily attributable to a decrease in the value of our common stock price at September 30, 2015 as compared to June 30, 2015. For the nine months ended September 30, 2015, we recorded a gain of \$0.6 million related to the change in fair value of our warrant liability, which was primarily attributable to a decrease in the value of our common stock price at September 30, 2015 as compared to December 31, 2014.

We recorded a gain of \$7.0 million for the quarter ended September 30, 2015 related to the change in fair value of our Series B preferred stock derivative liability. This gain was primarily attributable to a decrease in the value of our common stock price at September 30, 2015 as compared to June 30, 2015. For the nine months ended September 30, 2015, we recorded a gain of \$8.7 million related to the change in fair value of our Series B preferred stock derivative liability, with this gain primarily attributable to a decrease in the value of our common stock price at September 30, 2015 as compared to December 31, 2014.

We recorded a gain of \$7.1 million for the quarter ended September 30, 2014 related to the change in fair value of our warrant liability, which was primarily attributable to a decrease in the value of our common stock price at September 30, 2014 as compared to June 30, 2014. For the nine months ended September 30, 2014, we recorded a gain of \$9.2 million related to the change in fair value of our warrant liability, which was primarily attributable to a decline in the value of our common stock at September 30, 2014 as compared to December 31, 2013.

We recorded a gain of \$19.4 million for the quarter ended September 30, 2014 related to the change in fair value of our Series B preferred stock derivative liability. This gain was primarily attributable to a decrease in the price of our common stock at September 30, 2014 as compared to June 30, 2014. For the nine months ended September 30, 2014,

we recorded a gain of \$26.0 million related to the change in fair value of our Series B preferred stock derivative liability. This gain was primarily attributable to a decrease in the price of our common stock at September 30, 2014 as compared to December 31, 2013.

We will continue to adjust the liability related to our outstanding Series 2011 warrants 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 Series B preferred stock derivative feature until the conversion of our Series B preferred stock into common stock.

We also recorded expenses of \$0.3 million for the nine months ended September 30, 2015 consisting of placement agent costs of \$0.4 million 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, partially offset by a gain of \$0.1 million related to the re-valuation of liquidated damage liabilities associated with the March 2015 warrants.

### *Liquidity and Capital Resources*

We have incurred net losses since inception through September 30, 2015 of \$360.3 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 \$11.7 million and \$6.6 million at September 30, 2015 and December 31, 2014, respectively.

Net cash used in operating activities for the nine months ended September 30, 2015 was \$7.5 million. We recorded net income for the period of \$1.7 million, including a non-cash gain on warrant liability of \$0.6 million, a non-cash gain on Series B preferred stock derivative liability of \$8.7 million, and a non-cash gain of \$0.1 million related to the re-valuation of a liquidated damages liability. Non-cash charges for warrants issued to placement agents related to our March 2015 private placement of common stock, stock-based compensation expense, depreciation expense, and patent amortization expense, which collectively represented a source of cash of approximately \$0.7 million. An increase in prepaid expenses and other current assets, primarily related to accrued Australian government research and development grants, along with decreases in accounts payable, accrued expenses and other and accrued severance were partially offset by a reduction in accounts receivable and collectively represented a \$0.5 million use of cash used in operating activities during the nine months ended September 30, 2015.

Net cash used in investing activities was \$0.2 million and \$1.2 million for the nine months ended September 30, 2015 and September 30, 2014, respectively. Net cash used in investing activities for the nine months ended September 30, 2014 was primarily attributable to the build-out of our facility and the purchase of equipment for our Slovenia manufacturing facility.



Cash provided by financing activities for the nine months ended September 30, 2015 totaled \$12.8 million, and was comprised of the 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 cash expenses related to the issuance of approximately \$0.6 million. We also received \$0.4 million in proceeds from the exercise of warrants during this period.

We expect to need to raise additional capital or incur indebtedness to continue to fund our future operations. We may seek to raise capital through a variety of sources, including:

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

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

Our ability to raise additional funds will depend on our clinical and regulatory events, our ability to identify promising in-licensing opportunities and 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 satisfactory terms. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back or eliminate

some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

### *Contractual Obligations and Commitments*

As of September 30, 2015, there have been no material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed within “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, as contained in our Annual Report on Form 10-K for the year ended December 31, 2014.

### *Off-Balance Sheet Arrangements*

As of September 30, 2015, we did not have off-balance sheet arrangements.

### **Recent Accounting Pronouncements**

Refer to footnotes.

### **Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company as defined by Rule 12b-2 of 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 effective at the reasonable assurance level during the period covered by this report.

#### ***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. Based on that evaluations, there were no changes in our internal control over financial reporting during the latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than the following:

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. Although efforts remain in process, steps taken during the last fiscal quarter and earlier in 2015 that resulted in improvements to our internal control over financial reporting included the following:

- To address a prior material weakness related to accounting for complex and non-routine transactions, resulting in the conclusion that our internal control over financial reporting was not effective as of December 31, 2014, we engaged consultants with experience in accounting for more complex financial instruments and other complex accounting matters, to provide more resources for these accounting matters;
- We employed new financial reporting processes and procedures;
- We employed new accounting processes and control procedures; and

- We revisited and updated existing accounting policies and procedures.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

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

## Item 1A. Risk Factors

*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 (\*) 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, 2014. If any of the following risks actually occurs, 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 Business

*We are seeking to develop antibacterial agents using bacteriophage technology, which has not resulted in any approved product on the market to date.*

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 U.S. Food and Drug Administration, or 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, making claims of improved cure rates open for debate. 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 conduct efficiently the clinical trials required to obtain regulatory approval of our products, 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 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. We do not know whether planned clinical trials will be commenced or completed on schedule, if 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;

- delays in the commencement of clinical trials as a result of clinical trial holds or the need to obtain additional information to complete an Investigational New Drug Application (IND);

- delays in obtaining regulatory approval to commence new trials;

- adverse safety events experienced during our clinical trials;

- delays in obtaining clinical materials;

- slower than expected patient recruitment for participation in clinical trials; and

- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval.

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

***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 bacteriophage that target the desired bacteria for that product candidate. The selection of bacteriophage 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.



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

Our consolidated financial statements for the periods ended September 30, 2015 and December 31, 2014 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.

In December 2013, we completed a private placement of shares of our common stock, which raised approximately \$18.0 million, prior to commissions. In March 2015, we completed a private placement of shares of our common stock and warrants, which raised approximately \$13 million, prior to commissions. 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, 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. We believe that our existing resources are sufficient to fund our planned operations through the third quarter 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 obtaining 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 seek additional capital to support our product development activities. 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, if at all.

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

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

Our ability to raise additional funds will depend, in part, on the status of our product development activities and other business operations, 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 satisfactory terms, if at all. Raising additional capital through the sale of securities could cause significant dilution to our stockholders. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through additional arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, we may have to delay, reduce the scope of or eliminate some of our research and development, which could delay the time to market for any of our product candidates, if adequate funds are not available.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

***Preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not predict the results of subsequent human clinical trials.\****

Preclinical studies, including studies of our product candidates in animal models of disease, 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 Phase 1/2 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.

***Our product candidates must undergo rigorous clinical testing, the results of which are uncertain and could substantially delay or prevent us from bringing them to market.***

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;
- enrollment in our clinical trials for our product candidates may be slower than we anticipate, resulting in significant delays and additional expense;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- the effects of our product candidates on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use, if approved.

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 investigational drug 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 by clinical trial programs 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 must continue to develop manufacturing processes for our lead product candidates and any delay in or our inability to do so would result in delays in our clinical trials and materially and negatively affect our business and results.\****

We are developing novel manufacturing processes for the production of AB-SA01 for treatment of *S. aureus* (including MRSA) infections, AB-PA01 for the treatment of *P. aeruginosa* infections and AB-CD01 for the treatment of *C. difficile* infections at facilities 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 facilities 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 FDA's current good manufacturing practice regulations, or cGMP regulations, before the respective product candidates can be approved for use in clinical trials or commercialization. We have received GMP certification from JAZMP to manufacture bacteriophage drug substances and sterile final products. We will also be subject to additional inspections for GMP compliance for our other product candidates, and may be subject to additional inspections for AB-SA01. 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 facilities 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 may conduct one or more of our clinical trials 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 planning to conduct 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.

***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 10, 2015, we had twenty-four employees. Our success will depend on our ability to retain and motivate remaining 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 Financial Performance and Operations**

***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, and Biocontrol had an accumulated deficit of \$6.9 million. Since January 2011 through September 30, 2015, we have incurred a cumulative deficit of \$46.5 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 nine months ended September 30, 2015 we had an operating loss of \$7.3 million and a net income of \$1.7 million, including a non-cash gain on warrant and derivative liabilities of \$9.3 million. 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”.

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, we would be



unable to continue our research and development programs.

***We may be required to make cash payments to the holders of our Series B redeemable convertible preferred stock.\****

The holders of our shares of Series B redeemable convertible preferred stock (Series B) are entitled to receive accruing, cumulative dividends at the rate of 10% per annum, payable in cash at the option of the holders of two-thirds of the shares of Series B (a) when, as and if declared by our Board of Directors, (b) upon an acquisition of our company or (c) upon redemption of the Series B. In addition, if holders of Series B elect to convert their shares to common stock, or if the Series B is automatically converted to common stock in connection with a qualified public offering by us, all accrued but unpaid dividends on the Series B will become payable upon conversion. If such holders elect to receive payment for such dividends in cash, or if dividends are required to be paid upon conversion, we will have less cash available, which will have a negative effect on our operations and financial results. As of September 30, 2015, the aggregate amount of accrued but unpaid dividends on the Series B was \$2.9 million.

***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.\****

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 year ended December 31, 2013 and the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014, we determined that we had a material weakness as of December 31, 2014, namely that our controls over the evaluation and review of complex and non-routine transactions were not effective.

Due to this material weakness, we concluded that as of December 31, 2014, our internal control over financial reporting were not effective. Subsequent to December 31, 2014, we restated our consolidated financial statements as of December 31, 2013, March 31, 2014, June 30, 2014 and September 30, 2014 to correct for errors caused by this weakness.

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. 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.

If we are unable to successfully remediate any significant deficiency or material weakness in our internal control over financial reporting, identify any additional significant deficiencies or material weaknesses that may exist, or satisfy the requirements of the Sarbanes-Oxley Act, 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 in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

### **Risks Related to Our Dependence 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, and we have an agreement with Intrexon regarding the development of bacteriophage and new strains of manufacturing hosts for our phage therapies. 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 some of 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. There are numerous alternative sources to provide these services. 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 file New Drug Applications, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.



***We will rely on the U.S. Army to conduct a Phase 1 clinical trial, and their failure to perform in a timely manner may significantly delay the Staphylococcus aureus clinical program.\****

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 expect to utilize U.S. Army human resources and facilities to conduct our planned Phase 1 clinical trial of AB-SA01. Due to recent outbreaks of the Ebola virus, the Army has diverted significant resources to studying this potential epidemic. As a result, the U.S. Army has advised the Company that there may be a delay in initiating the planned Phase 1 AB-SA01 study, which may significantly affect our ability to conduct this clinical trial prior to the fourth quarter of 2015.

### **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.

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 have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we might not have been the first to file patent applications for these 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.

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the Generating Antibiotics Incentives Now Act, or the GAIN Act. The GAIN 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 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 shares 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. First, 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 our common shares are sold on the market without commensurate demand. Secondly, we are 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. As a consequence of this enhanced risk, more risk-averse 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 shares, 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 shares will sustain their current market prices, or as to what effect that the sale of shares or the availability of common shares 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;
- sales of our common stock by our executive officers, directors and five percent 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.

***A significant number of shares of our common stock are subject to issuance upon exercise or conversion of outstanding warrants, options and convertible securities, which upon such exercise or conversion may result in dilution to our security holders.\****

As of September 30, 2015, we have outstanding warrants to purchase 1,209,681 shares of our common stock at an average exercise price of \$9.90 per share, and outstanding options to purchase 635,401 shares of our common stock at an average exercise price of \$9.06 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 at this time which of these warrants will ultimately be exercised, it is reasonable to assume that such warrants will be exercised only if the exercise price is below the market price of our common stock. To the extent the warrants are exercised, additional shares of our common stock will be issued that will be eligible for resale in the public market, 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.

As of September 30, 2015, we have 7,527,853 outstanding shares of Series B redeemable convertible preferred stock. Each share of Series B redeemable convertible preferred stock is convertible into 0.2 shares of common stock and accrues dividends at the rate of 10% per year. At September 30, 2015, these shares would be convertible into 1,505,571 shares of common stock and the accrued dividends on these shares totaled \$2.5 million.

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

As of September 30, 2015, our executive officers, directors, 5% stockholders and their affiliates beneficially owned a majority 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 determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or 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.

***Our current articles of incorporation and bylaws and Washington law provisions that could 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;
- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; 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 shareholders owning ten percent (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 acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders 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. In addition, pursuant to our Articles of Incorporation we are not permitted to pay cash dividends on our common stock until all accrued dividends on the outstanding Series B shares have been paid in full. 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 Securities Exchange Act of 1934, as amended, or 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 two security 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.

We could be an “emerging growth company” for up to five years, although we may lose such status earlier, depending on the occurrence of certain events. We will remain an “emerging growth company” until the earliest to occur of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering conducted after we became a reporting company under the Exchange Act pursuant to our registration statement on Form 10 (File No. 000-23930), (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a “large accelerated filer” under the Exchange Act, which means that the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30<sup>th</sup> of the prior year, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

We cannot predict if investors will find our common stock less attractive or our company less comparable to certain other public companies because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, “emerging growth companies” can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.”

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

Pursuant to our Articles of Incorporation, we are not permitted to pay cash dividends on our common stock until all accrued dividends on the outstanding Series B shares have been paid in full.

## **Item 3. Defaults upon Senior Securities**

None.

## **Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

See the Exhibit Index following the signature page of this report, which is incorporated herein by reference.

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**SIGNATURES**

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

AMPLIPHI BIOSCIENCES  
CORPORATION

Date: November 16, 2015 By/s/ Michael Scott Salka  
Name: Michael Scott Salka  
Title: Chief Executive Officer  
(Principal Executive Officer)

By/s/ David E. Boshier  
Name: David E. Boshier  
Title: Chief Financial Officer  
(Principal Financial Officer)

**EXHIBIT INDEX**

Number	Description
3.1	Amended and Restated Articles of Incorporation of the Registrant, as amended.
3.2	Amended and Restated Bylaws of the Registrant, as amended.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen stock certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 10 (File No. 000-23930), filed with the SEC on December 16, 2013).
4.3	Form of Warrant to Purchase Shares of Common Stock issued to purchasers in December 2013 private placement (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form 10 (File No. 000-23930), filed with the SEC on December 16, 2013).
4.4	Registration Rights Agreement, dated December 16, 2013, by and among the Registrant and certain purchasers of the Registrant's Series B Convertible Preferred Stock (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form 10 (File No. 000-23930) , filed with the SEC on December 16, 2013).
4.5	Subscription Agreement to Purchase Series B Preferred Stock and Warrants, dated December 16, 2013, by and between the Registrant and the purchasers named therein (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form 10 (File No. 000-23930), filed with the SEC December 16, 2013).
4.6	Subscription Agreement to Purchase Common Stock, dated March 10, 2015, by and between the Registrant and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 19, 2015).
4.7	Form of Common Stock Warrant issued to purchasers in March 2015 private placement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 19, 2015).
4.8	Registration Rights Agreement, dated March 10, 2015, by and between the Registrant and purchasers of common stock in March 2015 private placement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 19, 2015).
10.1+	Consulting Agreement, dated September 3, 2015, by and between the Registrant and Wendy S. Johnson.
31.1	Certification of the Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).

32.1 Certification of the Principal Executive Officer Required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. 1350.

32.2 Certification of the Principal Financial Officer Required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. 1350.

101.INS XBRL Instance Document.

101.SCH XBRL Taxonomy Extension Schema Document.

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF XBRL Taxonomy Extension Definition Linkbase Document.

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

101.LAB XBRL Taxonomy Extension Label Linkbase Document.

+ Indicates management contractor or compensatory plan.