AmpliPhi Biosciences Corp
Form 10-Q
November 08, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

For the quarterly period ended September 30, 2018

OR

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

For the transition period from _____ to _____

**Commission file number: 001-37544**

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

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

incorporation or organization)

**3579 Valley Centre Drive, Suite 100**

**San Diego, California**
(Address of principal executive offices)

**92130**
(Zip Code)

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

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

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).

Yes x No ¨

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ¨ | Accelerated filer | ¨ |
| | | Smaller reporting company | x |
| Non-accelerated filer | x | | |
| | | Emerging growth company | x |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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

Yes ¨ No x

The number of shares of the Registrant's Common Stock, par value $0.01 per share, outstanding at November 5, 2018 was 32,293,308.

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**AmpliPhi Biosciences Corporation**

**Consolidated Balance Sheets**

| | September 30, 2018 (Unaudited) | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | $ 4,499,000 | $ 5,132,000 |
| Prepaid expenses and other current assets | 615,000 | 253,000 |
| Total current assets | 5,114,000 | 5,385,000 |
| Property and equipment, net | 591,000 | 816,000 |
| In-process research and development | 4,661,000 | 4,661,000 |
| Acquired patents, net | 253,000 | 276,000 |
| Total assets | $ 10,619,000 | $ 11,138,000 |
| | | |
| Liabilities and stockholders' equity | | |
| Current liabilities | | |
| Accounts payable | $ 714,000 | $ 578,000 |
| Accrued expenses | 1,751,000 | 1,390,000 |
| Total current liabilities | 2,465,000 | 1,968,000 |
| Derivative liabilities | 154,000 | 292,000 |
| Deferred tax liability | 1,147,000 | 1,147,000 |
| Total liabilities | 3,766,000 | 3,407,000 |
| | | |
| Stockholders' equity | | |
| Common stock, $0.01 par value; 67,000,000 shares authorized at September 30, 2018 and December 31, 2017; 16,468,308 and 9,498,928 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | 165,000 | 95,000 |
| Additional paid-in capital | 408,684,000 | 401,842,000 |
| Accumulated deficit | (401,996,000) | (394,206,000) |
| Total stockholders' equity | 6,853,000 | 7,731,000 |
| Total liabilities and stockholders' equity | $ 10,619,000 | $ 11,138,000 |

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, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| | **(Unaudited)** | **(Unaudited)** | **(Unaudited)** | **(Unaudited)** |
| Revenue | $- | $ 38,000 | $- | $95,000 |
| Operating expenses | | | | |
| Research and development (benefit) | 361,000 | (829,000) | 3,517,000 | 1,791,000 |
| General and administrative | 1,276,000 | 1,613,000 | 4,227,000 | 6,295,000 |
| Impairment charges | - | - | - | 5,800,000 |
| Total operating expenses | 1,637,000 | 784,000 | 7,744,000 | 13,886,000 |
| Loss from operations | (1,637,000) | (746,000) | (7,744,000) | (13,791,000) |
| Other income (expense) | | | | |
| Change in fair value of derivative liabilities | 31,000 | (37,000) | (46,000) | 1,997,000 |
| Other income, net | - | 4,000 | - | 6,000 |
| Total other income (expense), net | 31,000 | (33,000) | (46,000) | 2,003,000 |
| Loss before income taxes | (1,606,000) | (779,000) | (7,790,000) | (11,788,000) |
| Income tax benefit | - | - | - | 1,302,000 |
| Net loss | $(1,606,000) | $ (779,000) | $(7,790,000) | $(10,486,000) |
| Per share information: | | | | |
| Net loss per share, basic | $(0.10) | $ (0.09) | $(0.51) | $(1.97) |
| Weighted average shares outstanding, basic | 16,468,308 | 8,874,813 | 15,418,146 | 5,326,139 |
| Net loss per share, diluted | $(0.10) | $ (0.09) | $(0.51) | $(2.18) |
| Weighted average shares outstanding, diluted | 16,496,957 | 8,874,813 | 15,418,146 | 5,518,847 |

See accompanying condensed notes to consolidated financial statements.

**AmpliPhi Biosciences Corporation**

**Consolidated Statements of Cash Flows**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2018 (Unaudited)** | **2017 (Unaudited)** |
| Operating activities: | | |
| Net loss | $ (7,790,000) | $ (10,486,000) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Change in fair value of derivative liabilities | 46,000 | (1,997,000) |
| Stock-based compensation | 366,000 | 568,000 |
| Charge for common stock issuance (Note 6) | - | 519,000 |
| Depreciation | 268,000 | 255,000 |
| Amortization of patents | 23,000 | 23,000 |
| Other non-cash adjustments, net | - | 22,000 |
| Impairment charges | - | 5,800,000 |
| Deferred taxes | - | (1,302,000) |
| Changes in operating assets and liabilities: | | |
| Accounts payable and accrued expenses | 218,000 | (595,000) |
| Prepaid expenses and other current assets | (85,000) | 370,000 |
| Net cash used in operating activities | (6,954,000) | (6,823,000) |
| Investing activities: | | |
| Purchases of property and equipment | (41,000) | (40,000) |
| Net cash used in investing activities | (41,000) | (40,000) |
| Financing activities: | | |
| Proceeds from sale of common stock and related warrants, net of offering costs | 6,159,000 | 9,353,000 |
| Proceeds from exercises of warrants | 198,000 | 31,000 |
| Proceeds from stock issuance under employee stock purchase plan | 5,000 | 3,000 |
| Principal payments on note payable | - | (510,000) |
| Net cash provided by financing activities | 6,362,000 | 8,877,000 |
| Net increase (decrease) in cash and cash equivalents | (633,000) | 2,014,000 |
| Cash and cash equivalents, beginning of period | 5,132,000 | 5,711,000 |
| Cash and cash equivalents, end of period | $ 4,499,000 | $ 7,725,000 |
| Supplemental schedule of non-cash financing activities: | | |
| Offering costs included in accounts payable | $ 277,000 | $ - |

See accompanying condensed notes to consolidated financial statements.

**AmpliPhi Biosciences Corporation**

**Condensed Notes to Consolidated Financial Statements**
**(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 bind to and kill their bacterial targets.

**2. Liquidity**

The Company has prepared its consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, the Company has incurred net losses since its inception and has negative operating cash flows. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

As of September 30, 2018, the Company had cash and cash equivalents of $4.5 million. On October 16, 2018, the Company completed an underwritten public offering of common stock, pre-funded warrants and common warrants. The Company received aggregate gross proceeds from the offering of $6.8 million, before deducting the underwriting discount and commissions and other offering expenses payable by the Company (see Note 10). Considering the Company's current cash resources, including the net proceeds received from the public offering in October 2018, management believes the Company's existing resources will be sufficient to fund the Company's planned operations until mid-2019. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital.

**3. Significant Accounting Policies**

The Company's significant accounting policies are described in Note 3 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the

Securities and Exchange Commission ("SEC"). Since the date of those financial statements, there have been no material changes to the Company's significant accounting policies. The interim consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries Biocontrol Limited, Ampliphi Biotehnološke Raziskave in Razvoj d.o.o., and AmpliPhi Australia Pty Ltd. All significant intercompany accounts and transactions have been eliminated.

***Basis of Presentation***

The accompanying unaudited 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, 2017 included in the Company's Annual Report on Form 10-K, filed with the SEC. The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. 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 authoritative U.S. GAAP 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 consolidated financial statements include all adjustments that are of a normal and recurring nature and that are necessary for the fair presentation of the Company's financial position and the results of its operations and cash flows for the periods presented. Interim results are not necessarily indicative of results for the full year or any future period.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in its consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

***Research and Development Expenses***

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, salaries, costs of outside collaborators and outside services, allocated facility, occupancy and utility expenses, which are partially offset by the benefit of tax incentive payments for qualified research and development expenditures from the Australian tax authority ("AU Tax Rebates"). The Company does not record AU Tax Rebates until payment is received due to the uncertainty of receipt. The Company received AU Tax Rebates of

approximately $1.2 million and $2.0 million during the three months ended September 30, 2018 and 2017, respectively. AU Tax Rebates of $1.2 million have been recorded as an offset to research and development expense in the Company's consolidated statements of operations for the three and nine months ended September 30, 2018. AU Tax Rebates of $2.0 million have been recorded as an offset to research and development expense in the Company's consolidated statements of operations for the three and nine months ended September 30, 2017.

***Warrants***

Warrants are accounted for in accordance with the applicable accounting guidance provided in ASC 815 - *Derivatives and Hedging* as either derivative liabilities or as equity instruments depending on the specific terms of the warrants. Liability-classified instruments are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of derivative liabilities in the consolidated statements of operations (see Note 4).

***Recent Accounting Pronouncements Not Yet Adopted***

In February 2015, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which amends the FASB Accounting Standards Codification and creates Topic 842, "Leases." The new topic supersedes Topic 840, "Leases," and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and mandates a modified retrospective transition method. The Company plans to adopt this ASU on January 1, 2019. While the Company is still evaluating the timing and impact of the adoption of this guidance on its consolidated financial statements, it anticipates that the adoption could result in an increase in the assets and liabilities recorded on its consolidated balance sheet.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles - Goodwill and Other, Simplifying the Accounting for Goodwill Impairment*. ASU 2017-04 removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit’s carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. All other goodwill impairment guidance will remain largely unchanged. Entities will continue to have the option to perform a qualitative assessment to determine if a quantitative impairment test is necessary. This new guidance will be applied prospectively, and is effective for calendar year end companies in 2020. Early adoption is permitted for any impairment tests performed after January 1, 2017. Adoption of this ASU is not expected to have a material impact on the Company’s consolidated financial statements.

***Recently Adopted Accounting Standards***

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The ASU creates a single source of revenue guidance for companies in all industries. The new standard provides guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers, unless the contracts are within the scope of other accounting standards. It also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets. This guidance, as amended, must be adopted using either a full retrospective approach for all periods presented or a

modified retrospective approach and is effective for fiscal years beginning after December 15, 2017 with early adoption permitted. The Company adopted this ASU as of January 1, 2018 using the modified retrospective approach. As of January 1, 2018, the Company had no revenue contracts and therefore the adoption did not have an impact on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Cash Flow Statements, Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow classification issues with the objective of reducing diversity in practice. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company adopted this ASU as of January 1, 2018 and the adoption did not have an impact on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, which amends the FASB Accounting Standards Codification. Part I of ASU No. 2017-11, *Accounting for Certain Financial Instruments with Down Round Features*, changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The guidance is effective for reporting periods beginning after December 15, 2019 and interim periods within those fiscal years with early adoption permitted. The Company elected to early adopt this ASU as of January 1, 2018 and the adoption did not have an impact on the Company's consolidated financial statements. a

In June 2018, the FASB issued ASU No. 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which amends the FASB Accounting Standards Codification in order to simplify the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees will be aligned with the requirements for share-based payments granted to employees. The guidance mandates the modified retrospective approach and is effective for annual and interim reporting periods beginning after December 31, 2018, with early adoption permitted. The Company elected to early adopt this ASU as of June 30, 2018 and the adoption did not have an impact on the Company's consolidated financial statements.

**4. Fair Value Measurements**

The guidance regarding fair value measurements prioritizes the inputs used in measuring fair value and establishes a three-tier 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.

The Company estimates the fair values of derivative liabilities utilizing Level 3 inputs. No derivative liabilities have been transferred between the classification levels. Estimating the fair values of derivative liabilities requires the use of significant and subjective inputs that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. The recurring fair value measurements of the Company's derivative liabilities at September 30, 2018 and December 31, 2017 consisted of the following:

| | Quoted Prices in Active Markets for Identical Items (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
|---|---|---|---|---|
| September 30, 2018 | | | | |
| Liabilities | | | | |
| June 2016 offering warrant liability | $ - | $ - | $ 18,000 | $ 18,000 |
| November 2016 offering warrant liability | - | - | 136,000 | 136,000 |
| Total liabilities | $ - | $ - | $ 154,000 | $ 154,000 |
| | | | | |
| December 31, 2017 | | | | |
| Liabilities | | | | |
| June 2016 offering warrant liability | $ - | $ - | $ 32,000 | $ 32,000 |
| November 2016 offering warrant liability | - | - | 260,000 | 260,000 |
| Total liabilities | $ - | $ - | $ 292,000 | $ 292,000 |

The following table sets forth a summary of changes in the fair value of the Company's derivative liabilities:

| | June 2016 Offering Warrant Liability | November 2016 Offering Warrant Liability | Total Derivative Liabilities |
|---|---|---|---|
| Balance, December 31, 2017 | $ 32,000 | $ 260,000 | $ 292,000 |
| Changes in estimated fair value | (14,000) | 60,000 | 46,000 |
| Exercised warrants | - | (184,000) | (184,000) |
| Balance, September 30, 2018 | $ 18,000 | $ 136,000 | $ 154,000 |

The Company estimates the fair value of the June 2016 offering warrant liability at each reporting date using the Black-Scholes valuation model. Inputs used in this valuation model include the Company's stock price volatility, risk-free interest rates and expected term of the warrants.

Historically, the Company estimated the fair value of the November 2016 offering warrant liability at each reporting date using the Monte Carlo valuation model. Inputs used in the Monte Carlo valuation model included the Company's stock price volatility, risk-free interest rates and expected term of the warrants. Effective March 31, 2018, due primarily to the significant decrease in the number of warrants outstanding, the Company simplified the method used and changed to the Black Scholes valuation model, which approximates the Monte Carlo valuation model.

**5. Net Loss per Share**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Basic and diluted net loss per share calculation: | | | | |
| Net loss, basic | $(1,606,000) | $(779,000) | $(7,790,000) | $(10,486,000) |
| Change in fair value of November 2016 warrants | (21,000) | - | - | (1,546,000) |
| Net loss, diluted | $(1,627,000) | $(779,000) | $(7,790,000) | $(12,032,000) |
| Weighted average shares outstanding, basic | 16,468,308 | 8,874,813 | 15,418,146 | 5,326,139 |
| Net loss per share, basic | $(0.10) | $(0.09) | $(0.51) | $(1.97) |
| Weighted average shares outstanding, diluted | 16,496,957 | 8,874,813 | 15,418,146 | 5,518,847 |
| Net loss per share, diluted | $(0.10) | $(0.09) | $(0.51) | $(2.18) |

The following outstanding securities at September 30, 2018 and 2017 have been excluded from the computation of diluted weighted average shares outstanding for the three and nine months ended September 30, 2018 and 2017, as they would have been anti-dilutive:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Options | 1,149,164 | 1,116,765 | 1,149,164 | 1,116,765 |
| Warrants | 8,126,329 | 8,712,220 | 8,294,827 | 8,232,056 |
| Common stock (Note 6) | - | 523,210 | - | 523,210 |
| Total | 9,275,493 | 10,352,195 | 9,443,991 | 9,872,031 |

**6. Stockholders' Equity**

***Underwritten Public Offering of Common Stock, Pre-funded Warrants and Warrants***

On May 10, 2017, the Company completed an underwritten public offering and sold 2,584,085 shares of its common stock and 4,483,334 pre-funded warrants to purchase common stock in lieu of additional shares of common stock, and common warrants to purchase 8,000,000 shares of common stock. All of the pre-funded warrants were exercised during the year ended December 31, 2017. The combined price to the public for each share of common stock and accompanying common warrant was $1.50. The combined price to the public for each pre-funded warrant and

accompanying common warrant was $1.49. Each pre-funded warrant was exercisable for one share of common stock at an exercise price of $0.01 per share. The common warrants are exercisable at a price of $1.50 per share of common stock, and will expire five years from the date of issuance. The Company received net proceeds from the offering of approximately $9.4 million, after deducting $1.2 million in offering costs including the underwriting discount and commissions and other offering expenses payable by the Company. The Company evaluated the pre-funded warrants and common warrants issued in the May 2017 offering and determined that the warrants should be classified as equity instruments.

***Registered Offerings of Common Stock***

On January 12, 2018, the Company completed a registered public offering of 4,000,000 shares of its common stock at an offering price of $1.00 per share, for aggregate gross proceeds of $4.0 million. The Company received net proceeds from the offering of approximately $3.4 million, after deducting placement agent fees and other offering expenses payable by the Company. On March 22, 2018, the Company completed a registered direct offering of 2,743,640 shares of its common stock at an offering price of $1.10 per share, for aggregate gross proceeds of $3.0 million. The Company received net proceeds from the offering of approximately $2.8 million, after deducting placement agent fees and other offering expenses payable by the Company.

***Common Stock Issuance Agreement***

On April 8, 2016, the Company entered into the Common Stock Issuance Agreement (the "CSIA") with certain former holders of the Company's Series B redeemable convertible preferred stock (the "Holders"). Pursuant to terms of the CSIA, the Company agreed to issue a formula-based number of shares of its common stock to the Holders for no additional consideration upon completion of one or more bona fide equity financings in which the Company sells shares of its common stock below a specified price (a "Dilutive Issuance") in a transaction that occurs prior to the earlier of June 30, 2018 or such time as the Company has raised, following the date of the CSIA, $10.0 million in the aggregate (the "Price Protection Obligations"). In each of June 2016, November 2016 and May 2017, the Company completed offerings of its common stock that constituted Dilutive Issuances under the CSIA. Due in part to limitations on the number of shares issuable to the Holders under the rules of the NYSE American, no additional shares of common stock were issued to the holders in connection with the November 2016 and May 2017 offerings prior to June 2017.

On June 27, 2017, the Company and the Holders entered into an amendment to the CSIA (the "Amendment") to, among other things, terminate the Price Protection Obligations. In consideration for the termination of the Price Protection Obligations and a release of claims by the Holders, the Company agreed to (i) issue to the Holders, within five business days of the Amendment, an aggregate of 28,684 shares of its common stock (the "First Issuance"), which, under the rules of the NYSE American, was the maximum number of shares the Company was permitted to issue to the Holders pursuant to the CSIA without further shareholder approval, and (ii) issue to the Holders in a subsequent closing an aggregate 523,210 shares of common stock (the "Second Issuance"), subject to obtaining shareholder approval of the Second Issuance at the Company's 2017 Annual Meeting of Shareholders and the Company's receipt of a release of claims from the Holders at the time of the Second Issuance. On September 7, 2017 the Company's shareholders approved the Second Issuance. The Company received a release of claims from each of the Holders and issued 523,210 shares of common stock on September 19, 2017. The shares were valued at $519,000 as of September 19, 2017 based on the closing price of the Company's common stock of $0.99 per share at September 19, 2017 multiplied by the 523,210 shares of common stock issued to the Holders. The related charges of $111,000 and $519,000 were included as a component of general and administrative expense in the Company's consolidated statements of operations for the three and nine months ended September 30, 2017, respectively.

***Warrants***

At September 30, 2018, outstanding warrants to purchase shares of common stock, accounted for as equity or liabilities, are as follows:

| Shares Underlying Outstanding Warrants | Exercise Price | Expiration Date |
|---|---|---|

| | | | |
|---|---|---|---|
| 8,640 | $82.50 | | December 23, 2018 |
| 8,492 | $120.00 | | December 31, 2018 |
| 8,492 | $120.00 | | March 1, 2019 |
| 41,872 | $107.50 | | March 16, 2020 |
| 31,519 | $40.50 | | March 31, 2021 |
| 106,381 | $22.50 | | June 3, 2021 |
| 168,498 | $0.57 | (1) | November 22, 2021 |
| 7,920,933 | $1.50 | | May 10, 2022 |
| 8,294,827 | | | |

(1) The exercise price of the warrants is subject to adjustment upon future dilutive issuances of the Company's common stock and stock combination events as defined in an exercise price adjustment provision in the warrant agreements. The exercise price will be adjusted downward due to an event subsequent to September 30, 2018 (see Note 10).

During the nine months ended September 30, 2018, warrants to purchase 217,400 shares of the Company's common stock, originally issued in connection with the November 2016 and May 2017 public offerings, were exercised for proceeds to the Company of $198,000. During the nine months ended September 30, 2018, warrants to purchase 19,691 shares of the Company's common stock expired. The weighted average exercise price of outstanding warrants to purchase common stock at September 30, 2018 was $2.76 per share.

**7. Stock-Based Compensation**

***Stock Option Plan***

In June 2016, the Company's stockholders approved the 2016 Equity Incentive Plan (the "2016 Plan"). The 2016 Plan provides for the issuance of incentive awards in the form of non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance-based stock awards. The awards may be granted by the Company's Board of Directors to its employees, directors and officers and to consultants, agents, advisors and independent contractors who provide services to the Company or to a subsidiary of the Company. The exercise price for stock options must not be less than the fair market value of the underlying shares on the date of grant. Stock options expire no later than ten years from the date of grant and generally vest and typically become exercisable over a four-year period following the date of grant. Upon the exercise of stock options, the Company issues the resulting shares from shares reserved for issuance under the 2016 Plan. With the approval of the 2016 Plan, the remaining unallocated shares under the Company's 2013 Stock Incentive Plan were allocated to the 2016 Plan and an additional 100,000 new shares were added to the authorized share reserve under the 2016 Plan. Under the 2016 Plan, the number of shares authorized for issuance automatically increases annually beginning January 1, 2017 and through January 1, 2026. On January 1, 2018, the number of shares of common stock authorized for future issuance was automatically increased by 474,946 shares.

***Share-based Compensation***

The Company estimates the fair value of stock options with performance and service conditions using the Black-Scholes valuation model. Compensation expense related to stock options granted is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period.

The table below summarizes the total stock-based compensation expense included in the Company's consolidated statements of operations for the periods presented:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Research and development | $ 38,000 | $ 32,000 | $ 113,000 | $ 133,000 |
| General and administrative | 82,000 | 66,000 | 253,000 | 435,000 |
| Total stock-based compensation | $ 120,000 | $ 98,000 | $ 366,000 | $ 568,000 |

Stock option transactions during the nine months ended September 30, 2018 are presented below:

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2017 | 1,115,865 | $ 3.17 | 8.98 | |
| Granted | 36,500 | 1.20 | | |
| Forfeited/Cancelled | (3,201) | 11.02 | | |
| Outstanding at September 30, 2018 | 1,149,164 | $ 3.08 | 8.28 | $ 118,000 |
| Vested and expected to vest at September 30, 2018 | 864,051 | $ 3.80 | 8.03 | $ 90,000 |
| Exercisable at September 30, 2018 | 361,773 | $ 6.20 | 6.77 | $ 39,000 |

The aggregate intrinsic value of options at September 30, 2018 is based on the Company’s closing stock price on that date of $1.01 per share. As of September 30, 2018, there was $0.7 million of total unrecognized compensation expense related to unvested stock options, which the Company expects to recognize over the weighted average remaining period of 2.2 years.

***Shares Reserved For Future Issuance***

As of September 30, 2018, the Company had reserved shares of its common stock for future issuance as follows:

| | Shares Reserved |
|---|---|
| Stock options outstanding | 1,149,164 |
| Employee stock purchase plan | 47,172 |
| Available for future grants under the 2016 Plan | 447,127 |
| Warrants outstanding | 8,294,827 |
| Total shares reserved | 9,938,290 |

**8. Commitments and Contingencies**

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject the Company to costly legal expenses and, while management generally believes that there is adequate insurance to cover many different types of liabilities, the Company's insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company is currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our consolidated results of operations or financial position.

**9. Related Party**

On March 22, 2018, the Company completed a registered direct offering of 2,743,640 shares of its common stock at a price of $1.10 per share, including 181,820 shares sold to One Funds Management Limited as Trustee for Asia Pacific Healthcare Fund II ("One Funds"). Two members of the Company's board of directors are affiliated with One Funds.

**10. Subsequent Event**

On October 16, 2018, the Company completed an underwritten public offering and sold 14,875,000 shares of its common stock and 2,125,000 pre-funded warrants to purchase common stock, and common warrants to purchase 17,500,000 shares of common stock. The combined price to the public for each share of common stock and

accompanying common warrant was $0.40. The combined price to the public for each pre-funded warrant and accompanying common warrant was $0.39. Each pre-funded warrant is exercisable for one share of common stock at an exercise price of $0.01 per share. The common warrants are exercisable at a price of $0.40 per share of common stock, and will expire five years from the date of issuance. The Company received aggregate gross proceeds from the offering of $6.8 million, before deducting the underwriting discount and commissions and other offering expenses payable by the Company.

**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, 2017 included in our Annual Report on Form 10-K filed with the SEC.

Statements contained in this report that are not statements of historical fact are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, without limitation, statements concerning product development plans, clinical development plans, the use of bacteriophages to kill bacterial pathogens, having resources sufficient to fund our operations until mid-2019, future funding sources, general and administrative expenses, clinical trial and other research and development expenses, capital expenditures, the expected benefits of our targeted phage therapies strategy, tax credits and carry-forwards, and additional financings and litigation-related matters. Words such as "believe," "anticipate," "plan," "expect," "intend," "will," "
"potential" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. These statements are subject to risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. These forward-looking statements speak only as of the date on which they were made, and we undertake no obligation to update any forward-looking statements.

**Overview**

We are a clinical-stage biotechnology company focused on precisely targeted bacteriophage therapeutics for patients with serious and life-threatening antibiotic-resistant bacterial infections. Phages have a powerful and highly selective mechanism of action that enables them to bind to and kill specific bacteria. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current therapies, including the so-called multi-drug-resistant or "superbug" strains of bacteria. We are a leading developer of bacteriophage therapeutics. We are combining our expertise in the manufacture of drug-quality bacteriophages and our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages to develop state-of-the-art therapeutics. We are developing bacteriophage products to combat multi- or pan-drug-resistant bacterial pathogens, leveraging advances in sequencing and molecular biology. We have developed certain bacteriophage combinations that we believe maximize efficacy and minimize development of resistance. We currently have two product candidates in clinical development, AB-SA01 and AB-PA01 for the treatment of *Staphylococcus aureus,* or *S. aureus,* infections, including methicillin-resistant *S. aureus*, or MRSA, and *Pseudomonas aeruginosa*, or *P. aeruginosa,* infections, respectively. Based on funding availability, we would develop both product candidates for the treatment of serious or life-threatening, multi-drug resistant infections.

We believe our bacteriophage technology may have unique application in the area of targeted medicine, and in May 2017, we initiated a new strategic emphasis on targeted therapies for serious or life-threatening antibiotic-resistant infections. In particular, we believe our bacteriophage technology can be used to develop precisely targeted therapies for patients who suffer from serious or life-threatening antibiotic-resistant bacterial infections and who have limited or no other satisfactory treatment options. Moreover, we believe our ability to target bacteriophage therapies for antibiotic-resistant infections, combined with the ability of bacteriophage to disrupt biofilm and having the potential to re-sensitize drug-resistant populations to antibiotics, represents what could be a powerful tool against the growing global challenge of antibiotic-resistant infections.

Under existing single-patient expanded access guidelines (also referred to as “compassionate use”), established by the regulatory agencies, we have provided targeted phage therapies to patients suffering from severe antibiotic-resistant infections who have failed prior antibiotic therapies. We believe this strategic approach not only provides potential benefit to patients who have few or no other acceptable therapeutic options, but also generates the clinical and microbiological data from these cases that we expect to support the potential validation of the clinical utility of phage therapy, identify the most promising indications for further clinical development of our AB-SA01 and AB-PA01 product candidates for *S. aureus* and *P. aeruginosa*, define optimal treatment regimens, and inform our discussions with the U.S. Food and Drug Administration, or FDA, and other regulatory agencies in 2018 or later on defining a potential path to market approval. We are initially making targeted phage therapies available under the appropriate regulatory expanded access guidelines in the United States and in Australia, where we collaborate with select leading hospitals and key infectious disease physician opinion leaders to identify eligible patients. We believe that the United States and Australia have favorable regulatory frameworks and clinical expertise with respect to treating patients under single-patient expanded access guidelines.

We have generally incurred net losses since our inception and our operations to date have been primarily limited to research and development and raising capital. Since the shift in our focus to novel therapeutics in February 2011 through September 30, 2018, we have received approximately $65.4 million in net proceeds from the issuance of our equity securities and convertible debt securities. As of September 30, 2018, we had an accumulated deficit of $402.0 million, $86.5 million of which has been accumulated since January of 2011, when our company began its focus on bacteriophage development. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and obtaining regulatory approval of our product candidates.

We currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates, including through our targeted phage therapies strategy, and for working capital and other general corporate purposes.

We expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete development and obtain marketing approval for at least one of our product candidates.

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

On January 12, 2018, we completed a registered public offering of 4,000,000 shares of common stock at an offering price of $1.00 per share, for aggregate gross proceeds of $4.0 million. We received net proceeds from the offering of approximately $3.4 million, after deducting placement agent fees and other offering expenses payable by us. On March 22, 2018, we completed a registered direct offering of 2,743,640 shares of common stock at an offering price of $1.10 per share, for aggregate gross proceeds of $3.0 million. We received net proceeds from the offering of approximately $2.8 million, after deducting placement agent fees and other offering expenses payable by us.

**Recent Events**

In September 2018, we announced that we had received the official minutes from our August 2018 Type B Pre-IND meeting with the FDA regarding our proposed clinical development of AB-SA01 for the treatment of *S. aureus* bacteremia infections as well as patients with a hip or knee prosthetic joint infection due to *S. aureus*. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *S. aureus* bacteremia. The second such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered by intra-articular injection and then intravenously with the best available antibiotic therapy, compared to placebo plus the best available antibiotic therapy, in approximately 100 patients with a hip or knee prosthetic joint infection due to *S. aureus* as an adjunct to surgical treatment. We expect that we would produce our proprietary bacteriophage therapeutics for these clinical trials at our wholly owned manufacturing facility, which is good manufacturing practices (GMP) certified by the governmental authorities in the jurisdiction in which it operates. We believe our GMP-facility has the capacity to produce our proprietary bacteriophage therapeutics for these clinical trials through a potential filing of a biologics license application and potential approval.

In September 2018, we also received positive feedback from the FDA regarding our clinical development plans for AB-PA01 for the treatment of *P. aeruginosa* infections. Resistant *P. aeruginosa* is designated as ‘Priority 1: Critical’

pathogen on the World Health Organization's Priority Pathogens List and as 'Serious Threat' by the U.S. Centers for Disease Control and Prevention. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with hospital-acquired and ventilator-associated pneumonia due to *P. aeruginosa*. The second clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with P. aeruginosa bacteremia. We intend to seek non-dilutive financing and explore other opportunities to conduct these clinical trials.

In addition, in September 2018 we provided updated topline clinical results for our ongoing single-patient expanded access program. 84% of patients achieved treatment success (physician's assessment) at the end of bacteriophage therapy, defined as complete resolution or significant improvement of baseline signs and symptoms. We have now received clinical outcome results for 21 of the patients provided with our investigational bacteriophage therapeutics, across seven hospitals, and with serious or life-threatening infections not responding to antibiotic therapy.

On October 16, 2018, we completed an underwritten public offering in which we sold 14,875,000 shares of common stock and 2,125,000 pre-funded warrants to purchase common stock, and common warrants to purchase 17,500,000 shares of common stock. The combined price to the public for each share of common stock and accompanying common warrant was $0.40. The combined price to the public for each pre-funded warrant and accompanying common warrant was $0.39. Each pre-funded warrant is exercisable for one share of common stock at an exercise price of $0.01 per share. The common warrants are exercisable at a price of $0.40 per share of common stock, and will expire five years from the date of issuance. We received aggregate gross proceeds from the offering of $6.8 million, before deducting the underwriting discount and commissions and other offering expenses payable by us.

**Results of Operations**

**Comparison of three and nine months ended September 30, 2018 and 2017**

***Research and Development***

In July 2018, we received tax incentive payments of approximately $1.2 million from the Australian tax authority. Such tax incentive payments were based on eligible research and development expenditures incurred by our Australian subsidiary in 2017. In September 2017, we received tax incentive payments of approximately $2.0 million from the Australian tax authority, based on eligible research and development expenditures incurred by our Australian subsidiary in 2016. The tax incentive payments were recorded as an offset to research and development expense, resulting in net expense of $0.4 million for the three months ended September 30, 2018 and a net benefit of $0.8 million for the three months ended September 30, 2017. Research and development expenses, excluding any benefit from tax incentive payments, for the three months ended September 30, 2018 and 2017 were $1.6 million and $1.2 million, respectively. The increase of $0.4 million was primarily attributable to a $0.3 million increase in clinical costs and a $0.1 million increase in payroll-related costs.

Research and development expenses for the nine months ended September 30, 2018 were $3.5 million, net of approximately $1.2 million of incentive tax payments received from the Australian tax authority. Research and development expenses for the nine months ended September 30, 2017 were $1.8 million, net of approximately $2.0 million of incentive tax payments received from the Australian tax authority. Research and development expenses, excluding any benefit from tax incentive payments, for the nine months ended September 30, 2018 and 2017 were $4.7 million and $3.8 million, respectively. The increase of $0.9 million was primarily related to a $0.7 million increase in clinical costs, a $0.1 million increase in professional and consulting fees, and a $0.1 million increase in payroll-related costs.

***General and Administrative***

General and administrative expenses for the three months ended September 30, 2018 and 2017 were $1.3 million and $1.6 million, respectively. The decrease of $0.3 million was related to a $0.1 million decrease in professional fees. The decrease was also attributable to a $0.1 million non-cash charge during the three months ended September 30, 2017 related to the fair value of 523,210 shares of our common stock issued pursuant to the First Amendment of the Common Stock Issuance Agreement.

General and administrative expenses for the nine months ended September 30, 2018 and 2017 were $4.2 million and $6.3 million, respectively. The decrease of $2.1 million was primarily related to a $0.6 million decrease in payroll-related costs, a $0.5 million decrease in professional fees and a $0.2 million decrease in non-cash stock-based compensation expense. The decrease was also attributable to a $0.5 million non-cash charge during the nine months ended September 30, 2017 related to the fair value of 523,210 shares of our common stock issued pursuant to the First Amendment of the Common Stock Issuance Agreement.

***Impairment Charges***

There were no impairment charges during the three and nine months ended September 30, 2018. During the nine months ended September 30, 2017, we recorded a $5.8 million impairment charge, offset by a related income tax benefit of $1.3 million, relating to our IPR&D assets originally capitalized as a result of prior acquisitions of know-how and phage libraries. As of June 30, 2017, we assessed the fair value of our IPR&D assets and determined that the IPR&D assets were impaired. The impairment was due to an increase in our discount rate as compared to previous assessments due to the significant difference between our net assets and our market capitalization as of June 30, 2017. Due to this impairment, we recorded an impairment charge of $5.8 million, offset by a related income tax benefit of $1.3 million, in the second quarter of 2017. The IPR&D assets had a remaining book value of $4.7 million after the impairment charge, $2.8 million and $1.9 million for our Staphylococcal and Pseudomonas programs, respectively. We assessed the qualitative indicators for impairment as of September 30, 2018 and concluded that there were no negative operations indicators that would necessitate an interim impairment test for our research and development programs.

***Other Income (Expense)***

We recorded a loss of $46,000, net, for the nine months ended September 30, 2018, which was primarily related to a loss of $60,000 from the change in fair value of our derivative liability for warrants issued in November 2016.

We recorded a gain of $2.0 million for the nine months ended September 30, 2017, which was primarily related to a gain of $1.7 million from the change in fair value of our derivative liability for warrants issued in November 2016 and was attributable to a decrease in our stock price and downward adjustments in the exercise price during 2017.

***Income Taxes***

There was no income tax benefit for the three and nine months ended September 30, 2018 or for the three months ended September 30, 2017. The income tax benefit of $1.3 million for the nine months ended September 30, 2017 is related to a reduction of the existing deferred tax liability during the second quarter of 2017 as a result of a $5.8 million impairment charge for our IPR&D asset discussed above.

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***Liquidity, Capital Resources and Financial Condition***

We have prepared the accompanying consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. However, since our inception we have incurred net losses and had negative operating cash flows, and our accumulated deficit was $402.0 million as of September 30, 2018, $86.5 million of which has been accumulated since January of 2011 when we began our focus on bacteriophage development. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of the uncertainty concerning our ability to continue as a going concern.

We had cash and cash equivalents of $4.5 million at September 30, 2018. In October 2018, we completed an underwritten public offering of common stock, pre-funded warrants and common warrants, resulting in aggregate gross proceeds to us of $6.8 million. We believe our existing cash resources, after taking into account the net proceeds from our October 2018 public offering, will be sufficient to fund our planned operations until mid-2019. However, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

*Operating activities*

Net cash used in operating activities for the nine months ended September 30, 2018 was $7.0 million, as compared to $6.8 million for the nine months ended September 30, 2017. The increase of $0.2 million was due to an increase in payments related to research and development costs, net of incentive tax payments received from the Australian tax authority, offset by a decrease in payments related to general and administrative costs.

*Investing activities*

Net cash used in investing activities was $41,000 and $40,000 for the nine months ended September 30, 2018 and 2017, respectively, and was attributable to purchases of property and equipment.

*Financing activities*

Net cash provided by financing activities for the nine months ended September 30, 2018 was comprised of net cash proceeds of $6.2 million from our January 2018 and March 2018 offerings of common stock, after deducting offering costs paid of approximately $0.9 million. Net cash provided by financing activities also included cash proceeds of $0.2 million from the exercise of warrants for common stock.

Net cash provided by financing activities for the nine months ended September 30, 2017 was comprised of net cash proceeds of $9.4 million from our May 2017 underwritten public offering of common stock, pre-funded warrants and common warrants to purchase common stock, after deducting the underwriting discount and commissions and other expenses paid related to the offering of approximately $1.2 million.

**Future Capital Requirements**

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

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- manufacturing costs associated with our targeted phage therapies strategy and other research and development activities;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- whether and when we receive future Australian tax rebates, if any;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

We may seek funds through arrangements with collaborators or others that may require us to relinquish rights to the product 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 financings;
- collaborative arrangements or strategic financings;
- licensing arrangements; and
- public or private debt.

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

***Off-Balance Sheet Arrangements***

As of September 30, 2018, we did not have off-balance sheet arrangements.

**Recent Accounting Pronouncements**

Refer to *Note 3* of the condensed consolidated notes to the consolidated financial statements contained elsewhere in this report.

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

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

**Item 4. CONTROLS AND PROCEDURES**

***Disclosure Controls and Procedures***

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this quarterly report on Form 10Q. In designing and evaluating the disclosure controls and procedures, management recognized 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 and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2018.

***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.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, we are a party to certain litigation that is either judged to be not material or that arises in the ordinary course of business. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings.

### 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, 2017 as filed with the SEC. If any of the following risks actually occur, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.*

**Risks Related to Our Financial Condition and Need for Additional Capital**

***There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need to raise additional capital to support our operations.****

Our Annual Report on Form 10-K for the year ended December 31, 2017 includes disclosures and an opinion from our independent registered public accounting firm stating that our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2017 and September 30, 2018 were prepared under the assumption that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. At September 30, 2018, we had cash and cash equivalents of $4.5 million, and we have had recurring losses from operations and negative operating cash flows since inception. In October 2018, we completed an underwritten public offering of common stock, pre-funded warrants and common warrants, resulting in aggregate gross proceeds to us of $6.8 million.

We will need to raise additional capital to support our operations and product development activities. In the near term, we expect to continue to fund our operations, if at all, primarily through equity and debt financings in the future. We may also seek funds through arrangements with collaborators or others that may require us to relinquish rights to the product candidates that we might otherwise seek to develop or commercialize independently. If additional capital is not available to us when needed or on acceptable terms, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely. While we believe that our existing resources will be sufficient to fund our planned operations until mid-2019, we cannot provide assurances that our estimates are accurate, that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

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;
- manufacturing costs associated with our targeted phage therapies strategy and other research and development activities;

- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- whether and when we receive future Australian tax rebates, if any;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

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

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

Raising additional capital through the sale of securities could cause significant dilution to our stockholders. Any additional fundraising efforts may divert our management from their day to day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, on the success of our product development activities, including our targeted phage therapies strategy and any clinical trials we initiate, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

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

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

We have incurred losses in each year since our inception in 1992. As of September 30, 2018, our accumulated deficit was $402.0 million, $86.5 million of which has been accumulated since January of 2011, when we began our focus on bacteriophage development, 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, 2018 and 2017, we had losses from operations of $7.7 million and $13.8 million, respectively. Additional information regarding our results of operations may be found in our consolidated financial statements and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Item 2 in this report.

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

To attain ongoing profitability, we will need to develop products that receive regulatory approval, and market and sell such products 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 product sales and there is no guarantee that we will be able to do so in the future. If we fail to become profitable, or if we are unable to fund our continuing losses, our business, financial condition and results of operations may be materially adversely impacted and our stock price could decline.

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

Our ability to generate meaningful revenue and achieve profitability depends on our ability, and the ability of any third party with which we may partner, to successfully complete the development of, and obtain the regulatory

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

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

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

***The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

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

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

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double

taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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

As of December 31, 2017, we had federal net operating loss carryforwards of approximately $198.1 million, of which $7.3 million will expire in 2018 unless utilized, and the remaining carryforwards will expire in taxable years 2019 through 2037. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We believe we have experienced ownership changes in the past, including in connection with our November 2016, May 2017, January 2018 and March 2018 offerings, and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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

We are required to maintain internal control over financial reporting adequate to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with generally accepted accounting principles. 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. Material weaknesses in our internal controls have been identified in the past, and we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future.

If we are unable to maintain effective controls and procedures, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock.

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

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the NYSE American to implement provisions of the Sarbanes-Oxley Act, imposes significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These expenses will likely increase in the future, particularly after we cease to be an "emerging growth company" if we are also no longer a "smaller reporting company" as a result of additional corporate governance and disclosure requirements under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and SEC rules and regulations.

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

**Risks Related to Our Business**

***Results from preclinical studies and Phase 1 or 2 clinical trials of our product candidates or from single-patient expanded access treatments may not be predictive of the results of later stage clinical trials.****

Preclinical studies, including studies of our product candidates in animal disease models, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of prototype phage products in the treatment of bacterial infections, such as *P. aeruginosa* and *S. aureus,* may not predict the ability of these products to treat similar infections in humans. Despite promising data in our completed Phase 1 clinical trials, our phage technology may be found not to be efficacious in treating bacterial infections alone or in combination with other agents, when studied in later-stage clinical trials.

In addition, we have used and plan to continue to use our bacteriophage technology in the area of targeted medicine under single-patient expanded access guidelines, which permit the use of phage therapy outside of clinical trials, beginning in the United States and Australia and then potentially expanding to other countries. Despite prior single-patient expanded access successes, no assurance can be given that we will have similar single-patient expanded access treatment successes in the future. Single-patient expanded access is a term that is used to refer to the use of an investigational drug or therapy outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. Regulators often allow single-patient expanded access on a case-by-case basis for an individual patient or for defined groups of patients with similar treatment needs. In some countries, such as Australia, the treating physician can administer treatment under single-patient expanded access guidelines without pre-approval from the applicable regulatory authority.

In September 2018, we received the official minutes from our August 2018 Type B pre-IND meeting with the FDA regarding our AB-SA01 bacteriophage therapy product candidate. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *S. aureus* bacteremia. The second such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-SA01, administered by intra-articular injection and then intravenously with the best available antibiotic therapy, compared to placebo plus the best available antibiotic therapy, in approximately 100 patients with a hip or knee prosthetic joint infection due to *S. aureus* as an adjunct to surgical treatment. We are actively seeking and intend to continue to seek non-dilutive financing and explore other opportunities to conduct these clinical trials of AB-SA01. We intend to initiate the randomized clinical trial of AB-SA01 for *S. aureus* bacteremia in 2019. However, there can be no assurance that we will be able to obtain sufficient capital for such bacteremia trial, or that non-dilutive financing or other opportunities will be available to us, on a timely basis, on favorable terms, or at all. We may also choose to conduct one or more smaller-scale clinical trials of similar design as an alternative to conducting the approximately 100 patient clinical trials described above in an effort to reduce clinical trial expenditures. It is possible that results from such smaller-scale clinical trials may not be viewed by the FDA or other regulatory agencies as sufficient for the advancement of AB-SA01 into Phase 2 trials, including potentially registrational Phase 2 trials, due to the smaller trial populations even if the trial results are otherwise positive, which in turn could result in the FDA or other regulatory agencies requiring us to conduct additional studies beyond those that would have been required if we had conducted trials of approximately 100 patients as proposed in our August 2018 Type B pre-IND meeting.

In September 2018, we received positive feedback, via written response, from the FDA regarding our development plans for AB-PA01, without the need for a Type B pre-IND meeting. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with two proposed randomized clinical trials. The first such clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with hospital-acquired and ventilator-associated pneumonia (HAP/VAP) due to *P. aeruginosa*. The second clinical trial would be a Phase 1/2 randomized, controlled clinical trial to evaluate the safety and efficacy of AB-PA01, administered intravenously with the best available antibiotic therapy, compared to placebo plus best available antibiotic therapy, in approximately 100 patients with *P. aeruginosa* bacteremia. We intend to seek non-dilutive financing and explore other opportunities to conduct these clinical trials. However, there can be no assurance that such non-dilutive financing or other opportunities will be available to us on a timely basis, on favorable terms, or at all.

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 1 and Phase 2 trials, or in our single-patient expanded access program does not ensure that later clinical trials will be successful. Our initial results from early stage clinical trials or our single-patient expanded access program also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials and most product candidates that commence clinical trials are never approved for commercial sale.

***Our single-patient expanded access strategy may not be successful, which in turn could adversely affect our business.***

Our targeted phage therapies strategy involves providing phage therapy under single-patient expanded access guidelines to patients outside of clinical trials with antibiotic-resistant infections who have few or no other therapeutic options. We believe this strategic approach will not only provide potential benefit to patients to whom we are able to provide targeted phage therapies under the single-patient expanded access guidelines, but also provide the clinical data from these single-patient expanded access cases that we expect to support the potential validation of the clinical utility of phage therapy and inform our future discussions with the FDA in 2018 or later on defining a potential path to market approval. However, this program is subject to numerous risks and uncertainties, including the following:

- We have not established a cost reimbursement structure or otherwise entered into an arrangement that would at least offset our manufacturing costs for our phage therapies that may be administered to patients under single-patient expanded access guidelines. Increasing demand for our phage therapies in single-patient expanded access cases could result in significant costs to us.

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Responding to single-patient expanded access requests could divert attention of our personnel and use manufacturing resources that could otherwise be deployed in other development program activities.

- Single-patient expanded access treatment data may not establish proof-of-concept, and the FDA or other regulatory authorities may not accept single-patient expanded access data as sufficient clinical validation in support of our regulatory approval efforts, which could materially delay and increase the costs of our product development and commercialization activities.

- Patient access to phage therapy will be provided on an individual basis where physicians will make an application or post-treatment notification to the applicable regulatory authorities on a patient-by-patient basis. This can impose a significant administrative burden on participating physicians, who may be resistant to navigating a process with which they are unfamiliar. We may be unable to identify in a timely manner a sufficient number of patients who are eligible for expanded access emergency treatment and we may be unable to identify in a timely manner a sufficient number of physicians who are interested in providing experimental therapy to such patients, which may limit our ability to provide bacteriophage therapeutics under our expanded access program and to collect data from such cases.

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

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

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

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

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

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

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

- adverse safety events experienced during our clinical trials.

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

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

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

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

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

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

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

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

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

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and

- our product candidates may have unintended or undesirable effects on patients that may delay or preclude regulatory approval of our product candidates or limit their commercial use, if approved.

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

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

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

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

We completed an investigator-sponsored clinical trial of AB-SA01 at the University of Adelaide in Australia for CRS in December 2016. 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. Despite the positive feedback we received from the FDA in April 2017 regarding our proposal to commence a Phase 2 clinical trial of AB-SA01 in the United States, there can be no assurances that the FDA would ultimately support any decision by us to pursue a Phase 2 clinical trial based on data we currently have available.

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

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

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

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

product recalls, product seizures, operating restrictions and criminal prosecution.

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

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

- compliance with differing or unexpected regulatory requirements for the development, manufacture and, if approved, commercialization of our product candidates;
- difficulties in staffing and managing foreign operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;

- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;

- workforce uncertainty in countries where labor unrest is more common than in the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;

- changes in diplomatic and trade relationships; and

- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

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

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

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

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. Our success will depend on our ability to retain and motivate personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We also face competition from other more well-funded and well-established businesses and we may also be viewed as a riskier choice from a job stability perspective due to our relative newer status than longer existing biotech and pharmaceutical companies. We may not

be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

***We must manage a geographically dispersed organization.***

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

***Our business and operations might be adversely affected by security breaches, including any cybersecurity incidents.***

We depend on the efficient and uninterrupted operation of our computer and communications systems, which we use for, among other things, sensitive company data, including our financial data, intellectual property and other proprietary business information.

While certain of our operations have business continuity and disaster recovery plans and other security measures intended to prevent and minimize the impact of IT-related interruptions, our IT infrastructure and the IT infrastructure of our consultants, contractors and vendors are vulnerable to damage from cyberattacks, computer viruses, unauthorized access, electrical failures and natural disasters or other catastrophic events. We could experience failures in our information systems and computer servers, which could result in an interruption of our normal business operations and require substantial expenditure of financial and administrative resources to remedy. System failures, accidents or security breaches can cause interruptions in our operations and can result in a material disruption of our targeted phage therapies, bacteriophage product candidates and other business operations. The loss of data from completed or future studies or clinical trials could result in delays in our research, development or regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the development of our product candidates could be delayed or otherwise adversely affected.

Even though we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. For example, we are not insured against terrorist attacks or cyberattacks. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay the development of our product candidates.

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**Risks Related to Our Reliance on Third Parties**

***We rely on third parties for aspects of product development.***

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

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

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

**Risks Related to Our Intellectual Property**

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

Our commercial success will depend in part on our ability to obtain and maintain patent protection sufficient to prevent others from marketing our product candidates, as well as to defend and enforce these patents against

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

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

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

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

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

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

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

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

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

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

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

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

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

**Risks Related to Our Industry**

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

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

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

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

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

their efforts towards the development of products that could be competitive with our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Risks Related to Our Common Stock**

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

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

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

- adverse results or delays in our clinical trials;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials or the manufacturing processes of our product candidates;
- announcements of technological innovations, patents or new products by our competitors;
- regulatory developments in the United States and foreign countries;

- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;
- our inability, or the perception by investors that we will be unable, to continue to meet all applicable requirements for continued listing of our common stock on the NYSE American, and the possible delisting of our common stock;
- sales of our common stock by our executive officers, directors and principal stockholders or sales of substantial amounts of common stock; and
- loss of any of our key scientific or management personnel.

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

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

As of September 30, 2018, we had outstanding common warrants to purchase an aggregate of 8,294,827 shares of our common stock at a weighted-average exercise price of $2.76 per share, and outstanding options to exercise 1,149,164 shares of our common stock at a weighted-average exercise price of $3.08 per share. Following the completion of our underwritten public offering in October 2018 in which we sold shares of our common stock at a price of $0.39 per share, the exercise price of warrants outstanding at September 30, 2018 and exercisable for 168,498 shares of our common stock was reduced from $0.57 per share to $0.39 per share in accordance with an exercise price adjustment feature contained in such warrants. The exercise price of such warrants is subject to further reduction in the future in connection with certain circumstances, including certain issuances of securities at a price less than the then-current exercise price, subdivisions and stock splits. After giving effect to the exercise price reduction resulting from our October 2018 public offering, the adjusted weighted-average exercise price of the common warrants outstanding as of September 30, 2018 is $2.75 per share. As of October 31, 2018, we had outstanding common warrants to purchase an aggregate of 25,794,827 shares of our common stock at a weighted-average exercise price of $1.16 per share, which includes the common warrants to purchase 17,500,000 shares of our common stock at an exercise price of $0.40 per share sold in our October 2018 public offering. As of October 31, 2018, there were also 1,175,000 pre-funded warrants outstanding, each exercisable for one share of our common stock at an aggregate purchase price per share of $0.39, of which $0.38 per share was pre-funded at the closing of our October 2018 public offering. Although we cannot determine when these warrants or options will ultimately be exercised, it is reasonable to assume that such warrants and options will be exercised only if the exercise price is below the market price of our common stock. To the extent any of our outstanding warrants or options are exercised, additional shares of our common stock will be issued that will generally be eligible for resale in the public market (subject to limitations under Rule 144 under the Securities Act for certain of our warrants and with respect to shares held by our affiliates), which will result in dilution to our security holders. The issuance of additional securities could also have an adverse effect on the market price of our common stock.

***We have a limited number of unreserved shares available for future issuance, which may impair our ability to conduct future financing and other transactions.****

Our amended and restated articles of incorporation currently authorize us to issue up to 67,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of October 31, 2018, we had a total of approximately 6,093,402 shares of common stock that were authorized, not reserved and available for future issuance. As described in our preliminary proxy statement filed with the SEC on October 26, 2018, our board of directors has approved an amendment to our amended and restated articles of incorporation to increase the number of our authorized shares of common stock from 67,000,000 to 217,000,000, and we are seeking approval of such amendment at our annual meeting of shareholders to be held on December 17, 2018. There is no guarantee that this amendment will be approved by our shareholders.

If we are unable to enter into new arrangements to issue shares of our common stock or securities convertible or exercisable into shares of our common stock, our ability to complete equity-based financings or other transactions that

involve the potential issuance of our common stock or securities convertible or exercisable into our common stock, will be limited. In lieu of issuing common stock or securities convertible into our common stock in any future equity financing transactions, we may need to issue some or all of our authorized but unissued shares of preferred stock, which would likely have superior rights, preferences and privileges to those of our common stock, or we may need to issue debt that is not convertible into shares of our common stock, which may require us to grant security interests in our assets and property and/or impose covenants upon us that restrict our business. If we are unable to issue additional shares of common stock or securities convertible or exercisable into our common stock, our ability to enter into strategic transactions such as acquisitions of companies or technologies, may also be limited. If we are unable to complete financing, strategic or other transactions due to our inability to issue additional shares of common stock or securities convertible or exercisable into our common stock, our financial condition and business prospects may be materially harmed.

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

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

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

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

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management

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

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

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules of the NYSE American. 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 American 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 securities analysts and may never obtain additional research coverage by other securities and industry analysts. If no additional securities or industry analysts commence coverage of our company, the trading price for our stock could be negatively impacted. If we obtain additional securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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

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

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 $1.07 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 30th 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."

***Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to decline.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

***Future sales and issuances of our common stock or rights to purchase common stock by us, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to decline.***

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or the perception that such sales could occur.

We expect that significant additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To the extent we raise additional capital by issuing equity or convertible securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2016 Equity Incentive Plan, or the 2016 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2016 Plan will automatically increase on January 1st of each year by up to 5% of all shares of our capital stock outstanding as of December 31st of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our Employee Stock Purchase Plan, or ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1st of each calendar year by the lessor of 1% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year and 30,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2016 Plan and ESPP each year. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

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

None.

**Item 3. Defaults upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

| Number | Description |
|---|---|
| 3.1 | Amended and Restated Articles of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q, filed on November 16, 2015). |
| 3.2 | Articles of Amendment to Amended and Restated Articles of Incorporation of the Registrant. |
| 3.3 | Amended and Restated Bylaws of the Registrant, as amended (incorporated by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q, filed on November 16, 2015). |
| 4.1 | Reference is made to Exhibits 3.1, 3.2 and 3.3. |
| 4.2 | Form of Common Stock Certificate (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-8 (File No. 333-217563), filed on May 1, 2017). |
| 4.3 | Form of Warrant to Purchase Shares of Common Stock issued to purchasers in June 2013, July 2013 and December 2013 in connection with private placements (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended). |
| 4.4 | Subscription Agreement to Purchase Series B Preferred Stock and Common Stock Warrants, dated June 26, 2013 (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended). |
| 4.5 | Registration Rights Agreement, dated December 16, 2013, by and among the Registrant and certain purchasers of the Registrant's Common Stock (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended). |
| 4.6 | Subscription Agreement to Purchase Common Stock and Warrants, dated December 16, 2013 (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended). |
| 4.7 | Subscription Agreement to Purchase Common Stock and Warrants, dated March 10, 2015 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed March 19, 2015). |
| 4.8 | Form of Common Stock Warrant issued to purchasers in March 2015 private placement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed March 19, 2015). |
| 4.9 | Registration Rights Agreement, dated March 10, 2015, by and among the Registrant and certain purchasers of the Registrant's Common Stock (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, filed March 19, 2015). |
| 4.10 | Form of Amendment to Warrants to Purchase Shares of Common Stock issued to purchasers in June 2013, July 2013 and December 2013 in connection with private placements (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on May 15, 2015). |
| 4.11 | Form of Warrant to Purchase Shares of Common Stock issued in connection with the Registrant's acquisition of Biocontrol Ltd in December 2011 (incorporated by reference to Exhibit 4.11 to the Annual Report on Form 10-K, filed on March 30, 2016). |
| 4.12 | Form of Warrant to Purchase Shares of Common Stock issued in connection with the issuance of convertible notes of the Registrant in February 2013, March 2013, April 2013 and May 2013 (incorporated by reference to Exhibit 4.12 to the Annual Report on Form 10-K, filed on March 30, 2016). |
| 4.13 | Form of Warrant to Purchase Shares of Common Stock issued in connection with the Registrant's acquisition of certain assets of Novolytics Limited in February 2016 (incorporated by reference to Exhibit 4.13 to the Annual Report on Form 10-K, filed on March 30, 2016). |
| 4.14 | Form of Warrant to Purchase Common Stock issued to purchasers in May 2016 registered direct offering (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed on June 1, 2016). |
| 4.15 | Form of Securities Purchase Agreement (incorporated by reference to Exhibit 99.3 to the Current Report on Form 8-K, filed on June 1, 2016). |
| 4.16 | |

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|---|---|
| | Form of Warrant to Purchase Common Stock issued to purchasers in November 2016 registered direct offering (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed on November 17, 2016). |
| 4.17 | Form of Warrant to Purchase Common Stock issued to purchasers in May 2017 (incorporated by reference to Exhibit 4.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-217169)). |
| 4.18 | Form of Pre-Funded Warrant issued to purchasers in October 2018 underwritten public offering (incorporated by reference to Exhibit 4.18 to the Registrant Registration Statement on Form S-1 (File No. 333-226959)). |
| 4.19 | Form of Warrant to Purchase Common Stock issued to purchasers in October 2018 underwritten public offering (incorporated by reference to Exhibit 4.19 to the Registrant Registration Statement on Form S-1 (File No. 333-226959)). |
| 31.1 | Certification of 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 Principal Executive Officer Required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. 1350. |
| 32.2 | Certification of 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. |

**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 8, 2018 By /s/ Paul C. Grint, M.D.
Name: Paul C. Grint, M.D.
Title: Chief Executive Officer
(Principal Executive Officer)

By /s/ Steve R. Martin
Name: Steve R. Martin
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)