

# ACHAAGEN INC

## FORM 10-Q (Quarterly Report)

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, DC 20549

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended **June 30, 2017**

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: **001-36323**

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**ACHAOGEN, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**68-0533693**  
(I.R.S. Employer  
Identification No.)

**1 Tower Place, Suite 300**  
**South San Francisco, CA**  
(Address of principal executive offices)

**94080**  
(Zip Code)

**(650) 800-3636**  
(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of August 2, 2017, there were 42,233,305 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

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**ACHAOGEN, INC.**  
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

**Achaogen, Inc.**  
**Condensed Consolidated Balance Sheets**  
*(In thousands except share and per share data)*

	<u>June 30, 2017</u> (unaudited)	<u>December 31, 2016</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 143,999	\$ 118,964
Short-term investments	86,295	26,912
Contracts receivable	1,117	12,151
Prepays and other current assets	7,810	2,189
Restricted cash	8,991	127
Total current assets	<u>248,212</u>	<u>160,343</u>
Property and equipment, net	11,415	3,261
Restricted cash	3,575	250
Deposit and other assets	—	71
Total assets	<u>\$ 263,202</u>	<u>\$ 163,925</u>
<b>Liabilities, contingently redeemable common stock and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 7,850	\$ 5,739
Accrued liabilities	8,385	9,698
Loan payable, current portion	10,417	4,167
Deferred Revenue	2,968	—
Other current liabilities	28	104
Total current liabilities	<u>29,648</u>	<u>19,708</u>
Loan payable, long-term	15,280	21,110
Warrant liability	23,043	13,874
Derivative liability	642	602
Deferred Rent	6,076	1,896
Total liabilities	<u>74,689</u>	<u>57,190</u>
Commitments and contingencies (Note 10)		
Contingently redeemable common stock (Note 9)	10,000	—
Stockholders' equity		
Common stock, \$0.001 par value, 290,000,000 shares authorized at June 30, 2017 and December 31, 2016; 42,232,087 and 35,638,052 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	42	35
Preferred stock, \$0.001 par value, 10,000,000 shares authorized and zero shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Additional paid-in-capital	485,061	353,927
Accumulated deficit	(306,548)	(247,220)
Accumulated other comprehensive loss	(42)	(7)
Total stockholders' equity	<u>178,513</u>	<u>106,735</u>
Total liabilities, contingently redeemable common stock and stockholders' equity	<u>\$ 263,202</u>	<u>\$ 163,925</u>

*See accompanying notes to condensed consolidated financial statements.*

**Achaogen, Inc.**  
**Condensed Consolidated Statements of Operations**  
*(In thousands except share and per share data)*  
*(unaudited)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Contract revenue	\$ 1,266	\$ 9,144	\$ 8,729	\$ 14,993
Operating expenses				
Research and development	22,199	21,708	40,797	35,601
General and administrative	8,860	3,951	15,609	7,728
Total operating expenses	31,059	25,659	56,406	43,329
Loss from operations	(29,793)	(16,515)	(47,677)	(28,336)
Interest expense	(723)	(447)	(1,430)	(885)
Change in warrant and derivative liabilities	4,225	(1,382)	(10,731)	(1,382)
Other income, net	221	76	510	138
Net loss	\$ (26,070)	\$ (18,268)	\$ (59,328)	\$ (30,465)
Net loss per common share (Note 2):				
Basic	\$ (0.68)	\$ (0.87)	\$ (1.61)	\$ (1.55)
Diluted	\$ (0.78)	\$ (0.87)	\$ (1.61)	\$ (1.55)
Weighted-average shares used to compute net loss per common share				
Basic	38,072,763	20,899,297	36,905,802	19,648,792
Diluted	39,092,279	20,899,297	36,905,802	19,648,792

*See accompanying notes to condensed consolidated financial statements.*

**Achaogen, Inc.**  
**Condensed Consolidated Statements of Comprehensive Loss**  
*(In thousands)*  
*(unaudited)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net Loss	\$ (26,070)	\$ (18,268)	\$ (59,328)	\$ (30,465)
Other comprehensive (loss) income:				
Net unrealized gain (loss) on available-for-sale securities	17	(2)	(36)	53
<b>Total comprehensive loss</b>	<b>\$ (26,053)</b>	<b>\$ (18,270)</b>	<b>\$ (59,364)</b>	<b>\$ (30,412)</b>

*See accompanying notes to condensed consolidated financial statements.*

**Achaogen, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
(In thousands)  
(unaudited)

	<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (59,328)	\$ (30,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	424	227
Amortization of premium (discount) on short-term investments	(65)	252
Stock-based compensation expense	6,424	1,751
Loss on fixed asset disposition	54	—
Change in warrant and derivative liabilities	10,730	1,382
Non-cash interest expense relating to notes payable	420	279
Change in operating assets and liabilities:		
Contracts receivable	11,034	(3,613)
Prepays and other assets	(5,550)	(510)
Accounts payable and accrued liabilities	(819)	6,996
Deferred revenue	2,968	—
Other liabilities	310	(108)
<b>Net cash used in operating activities</b>	<b>(33,398)</b>	<b>(23,809)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(3,221)	(317)
Purchase of short-term investments	(92,759)	—
Maturities of short-term investments	33,406	22,895
<b>Net cash used in investing activities</b>	<b>(62,574)</b>	<b>22,578</b>
<b>Cash flows from financing activities:</b>		
Proceeds from underwritten public offering, net of issuance costs	121,199	—
Proceeds from issuance of contingently redeemable common stock, net of issuance costs	10,000	—
Proceeds from issuance of common stock, net of issuance costs	—	25,420
Proceeds from the issuance of common stock in connection with equity incentive plans	1,709	173
Proceeds from issuance of loan payable	—	10,000
Proceeds from exercise of stock warrants	288	—
<b>Net cash provided by financing activities</b>	<b>133,196</b>	<b>35,593</b>
Net increase (decrease) in cash, cash equivalents, and restricted cash	37,224	34,362
Cash, cash equivalents, and restricted cash at beginning of period	119,341	20,414
<b>Cash, cash equivalents, and restricted cash at end of period</b>	<b>\$ 156,565</b>	<b>\$ 54,776</b>
<b>Supplemental disclosures of cash flow information</b>		
Interest paid	\$ 1,010	\$ 606
<b>Supplemental disclosures of noncash investing and financing information</b>		
Reclassification of warrant liability to additional paid-in capital	\$ 1,521	\$ —
Purchases of property plant and equipment included in deferred rent	\$ 3,794	\$ —

*See accompanying notes to condensed consolidated financial statements.*

Notes to Condensed Consolidated Financial Statements  
(unaudited)

**1. Organization and Basis of Presentation and Consolidation**

Achaogen, Inc. (together with its consolidated subsidiary, the “Company”) is a late-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel antibacterial treatments against multi-drug resistant gram-negative infections. The Company is developing plazomicin, its lead product candidate, for the treatment of bacterial infections due to multi-drug resistant Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae (“CRE”). The Company’s Phase 3 study of plazomicin in the treatment of patients with complicated urinary tract infections (“cUTI”) and acute pyelonephritis (“AP”), entitled EPIC (Evaluating Plazomicin In cUTI), is expected to serve as a single pivotal study supporting a new drug application (“NDA”) for plazomicin in the United States. In addition, the Company’s Phase 3 study of plazomicin, the CARE (Combating Antibiotic Resistant Enterobacteriaceae) trial, is a resistant pathogen-specific trial designed to evaluate the efficacy and safety of plazomicin in patients with infections due to CRE.

The Company was incorporated in Delaware in 2002 and commenced operations in 2004. Since commencing operations in 2004, the Company has devoted substantially all its resources to identifying and developing its product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations.

***Basis of Presentation and Consolidation***

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) and following the requirements of the Securities and Exchange Commission (the “SEC”) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company’s annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company’s financial information. The results of operations for the three-month and six-month periods ended June 30, 2017 are not necessarily indicative of the results to be expected for the full year or any other future period. The balance sheet as of December 31, 2016 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. Intercompany accounts and transactions have been eliminated upon consolidation.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2016 included in the Company’s Annual Report on Form 10-K.

***Liquidity and Going Concern***

On May 31, 2017, the Company completed an underwritten public offering of 5,750,000 shares of its common stock at a price to the public of \$22.50 per share, including the closing of the full exercise of the underwriters’ option to purchase an additional 750,000 shares of common stock on June 9, 2017. The Company received net proceeds from the offering of \$121.2 million, after deducting the underwriting discounts and commissions and offering expenses.

On May 4, 2017, the Company entered into an agreement with the Bill & Melinda Gates Foundation (the “Gates Foundation”) to discover drug candidates against gram-negative bacterial pathogens intended to prevent neonatal sepsis (the “Grant Agreement”). Pursuant to the Grant Agreement, the Gates Foundation awarded the Company up to approximately \$10.5 million in grant funding (“Grant Funds”) over a three-year research term, of which approximately \$3.2 million was received in May 2017 (the “Advance Funds”). Concurrently with the Grant Agreement, the Company entered into a Common Stock Purchase Agreement (the “Gates Purchase Agreement”) with the Gates Foundation, pursuant to which the Company agreed to sell 407,331 shares of its contingently redeemable common stock to the Gates Foundation in a private placement at a purchase price per share equal to \$24.55, for gross proceeds to the Company of \$10.0 million (“Gates Investment”).

In connection with the Grant Agreement and the Gates Investment, the Company entered into a strategic relationship with the Gates Foundation (the “Letter Agreement”). Under the terms of the Letter Agreement, the Gates Investment and Grant Funds may only be used to conduct mutually agreed upon work, including the scale up of the Company’s antibody platform technology to launch a product intended to prevent neonatal sepsis (the “NSP”). Pursuant to the Letter Agreement, the Company agreed to make the NSP available and accessible in certain developing countries and to grant the Gates Foundation a non-exclusive license to commercialize selected drug candidates in certain developing countries, which may only be exercised in the event of certain defaults as described in the Letter Agreement (the “Global Access Commitments”). The Global Access Commitments will continue in effect until the earlier

of 25 years from the closing of the Gates Investment or 7 years following the termination of all funding provided by the Gates Foundation; provided, that the Global Access Commitments will continue for any products or services developed with funding provided by the Gates Foundation which continue to be developed or available in certain developing countries.

On December 19, 2016, the Company completed an underwritten public offering of 7,475,000 shares of its common stock at a price to the public of \$13.50 per share, including the full exercise of the underwriters' option to purchase an additional 975,000 shares of common stock. The Company received net proceeds from the offering of \$94.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

On June 3, 2016, the Company sold 7,999,996 shares of its common stock and warrants to purchase 1,999,999 shares of its common stock pursuant to Securities Purchase Agreement (the "Purchase Agreement") for aggregate gross proceeds of \$25.4 million and aggregate net proceeds of \$25.1 million, after deducting the issuance costs, in connection with a private placement financing transaction (the "Private Placement"). The warrants have an exercise price of \$3.66 per share and are exercisable up to five years from the date of issuance.

On April 7, 2015, the Company filed a Registration Statement on Form S-3 (the "2015 Shelf Registration Statement"), which included a prospectus covering the offering, issuance and sale of up to \$30.0 million of shares of the Company's common stock from time to time in an "at-the-market" ("ATM") equity offering pursuant to a sales agreement with Cowen and Company, LLC. As of June 30, 2017, the Company had sold 1,105,549 shares pursuant to its ATM equity offering program at a weighted-average price of \$4.82 per share for aggregate offering proceeds of \$5.3 million and aggregate net proceeds of \$5.1 million, after deducting the sales commissions and offering expenses.

The Company has incurred losses and negative cash flows from operations every year since its inception. As of June 30, 2017, the Company had unrestricted cash, cash equivalents and short-term investments of approximately \$230.3 million and an accumulated deficit of approximately \$306.5 million. Management expects that, based on its current operating plans, the Company's existing cash, cash equivalents and short-term investments as of June 30, 2017 will be sufficient to fund its current planned operations for at least the next twelve months from the issuance of these financial statements. Management plans to raise additional funds through equity or debt financing arrangements, government contracts, and/or third party collaboration funding in the future to fund its operations, including the commercial development of plazomicin. However, there can be no assurance that such funding sources will be available at terms acceptable to the Company or at all. If the Company is unable to raise additional funding to meet its working capital needs, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

## **2. Summary of Significant Accounting Policies**

### *Use of Estimates*

The accompanying financial statements have been prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures of contingent liabilities. On an ongoing basis, management evaluates its estimates, including those related to clinical trial accruals, fair value of liabilities, common stock and stock-based awards and income taxes. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

### *Fair Value of Financial Instruments*

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, contracts receivable, prepaid and other current assets, accounts payable, accrued liabilities, and other current liabilities approximate fair value due to their short-term maturities. Short-term investments consist of available-for-sale securities and are carried at fair value. Based upon the borrowing rates (which is a Level 2 input) currently available to the Company for loans with similar terms, the Company believes the carrying amount of the loan payable approximates its fair value. The warrant and derivative liabilities are recorded at estimated fair value with changes in estimated fair value recorded in the Company's statements of operations.

### **Cash and Cash Equivalents**

Cash equivalents include only securities having a maturity of three months or less at the time of purchase. As of June 30, 2017 and December 31, 2016, cash and cash equivalents consisted of bank deposits, cash, commercial paper, cash repurchase agreement investments and investments in government obligations money market funds.

### **Short-term Investments**

Short-term investments consist of debt securities with maturities greater than three months, but less than one year from the date of acquisition, and are classified as available for sale. Short-term investments are carried at fair value. Unrealized gains and losses on available-for-sale securities are excluded from earnings and reported as a component of net unrealized gain (loss) on available-for-sale securities in the Company's consolidated statements of comprehensive loss. The amortized cost of debt securities reflects amortization of purchase premiums and accretion of purchase discounts to date, which are included in interest income.

The Company reviews all of its marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value.

### **Restricted Cash**

At June 30, 2017 and December 31, 2016, the Company had restricted cash of \$12.6 million and \$0.4 million, respectively. The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet that sum to the total of the same such amounts shown in the consolidated statements of cash flows (in thousands):

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Cash and cash equivalents	\$ 143,999	\$ 118,964
Restricted cash, current	8,991	127
Restricted cash, non-current	3,575	250
Total cash, cash equivalents, and restricted cash	<u>\$ 156,565</u>	<u>\$ 119,341</u>

As of June 30, 2017 and December 31, 2016, the Company had \$12.2 million and zero, respectively, of restricted cash related to the cash provided by the Gates Foundation, in connection with the Grant Agreement, Gates Purchase Agreement and Letter Agreement (see Note 1). As of June 30, 2017 and December 31, 2016, the Company had \$0.4 million of restricted cash, of which \$0.3 million relates to the current facility lease and \$0.1 million relates to the previous facility lease that expired on April 14, 2017.

Concurrently with the Grant Agreement, the Company entered into the Gates Purchase Agreement, pursuant to which the Company issued 407,331 shares of contingently redeemable common stock to the Gates Foundation for the Gates Investment (see Note 1). In addition, the Letter Agreement, among other things, restricts the Company's use of both the Grant Funds and the Gates Investment to expenditures, including an allocation of overhead and administrative expenses, that are reasonably attributable to the activities required to support the research projects funded by the Gates Foundation.

As a result of such restrictions, as of June 30, 2017, the Company classified the unspent portions of the Grant Funds and Gates Investment, held at one of the Company's financial institutions, as restricted cash. The restricted cash related to the Company's leases, which consists of money market accounts with one of the Company's financial institutions, serves as collateral for the letters of credit provided as security deposits under the Company's facility leases and expire approximately 90 days from their respective lease terms.

### **Warrant Liability**

On June 3, 2016, the Company issued warrants to purchase 1,999,999 shares of its common stock in connection with the Private Placement. Each warrant has an exercise price of \$3.66 per share and is exercisable for five years from the date of issuance. The Company accounts for these warrants as a liability instrument measured at estimated fair value. The initial fair value of the warrants was determined using a calibration model that involved using the Black-Scholes Pricing Model ("Black-Scholes"), which requires inputs such as the risk-free interest rate, expected share price volatility, underlying price per share of the Company's common stock and remaining term of the warrants. The warrants are subject to remeasurement at each balance sheet date, using Black-Scholes, with any changes in the fair value of the outstanding warrants recognized in the condensed consolidated statements of operations.

### **Segment Reporting**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The Company has one operating segment.

### ***Customer Concentration***

For the three-month and six-month periods ended June 30, 2017 and 2016, the Company's revenue was generated from funding pursuant to U.S. government contracts and a non-profit foundation grant, and accordingly all contracts receivable relate to funding from U.S. government contracts and a non-profit foundation grant.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash, cash equivalents and short-term investments. Cash and cash equivalents are deposited in checking and money market accounts at one financial institution with balances that generally exceed federally insured limits. Management believes that the financial institution is financially sound, and, accordingly, minimal credit risk exists with respect to this financial institution. The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of default by the institutions holding its cash and cash equivalents or issuing the debt securities. As of June 30, 2017 and December 31, 2016, the Company had not experienced any credit losses in such accounts or investments.

### ***Revenue Recognition***

The Company recognizes revenue when: (i) evidence of an arrangement exists, (ii) fees are fixed or determinable, (iii) services have been delivered, and (iv) collectability is reasonably assured. The Company currently generates revenue from government contracts and a non-profit foundation grant (collectively, the "Revenue Contracts"). Revenue Contracts are agreements that provide the Company with payments for certain types of expenditures in return for research and development activities over a contractually-defined period. Revenue from the Revenue Contracts is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the applicable conditions under the government contracts have been met. Costs of contract revenue are recorded as a component of operating expenses in the Company's consolidated statement of operations.

Funds received from third parties under contract arrangements are recorded as revenue if the Company is deemed to be the principal participant in the contract arrangements because the activities under the contracts are part of the Company's development programs. If the Company is not the principal participant, the funds from contracts are recorded as a reduction to research and development expense. Contract funds received are not refundable and are recognized when the related qualified research and development costs are incurred and when there is reasonable assurance that the funds will be received. Funds billed and received in advance are recorded as deferred revenue.

### ***Research and Development Costs***

Research and development costs are expensed as incurred. Research and development expenses include certain payroll and personnel expenses; laboratory supplies; consulting costs; external contract research and development expenses; and allocated overhead, including rent, equipment depreciation and utilities, and relate to both Company-sponsored programs as well as costs incurred pursuant to collaboration agreements and government contracts.

The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Advance payments for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses and other current assets and recognized as an expense as the goods are delivered or the related services are performed.

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

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which, for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. This ASU will be effective for the Company in fiscal year 2019. Early adoption is permitted. The Company is currently assessing the potential effects of this ASU on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede

most current revenue recognition guidance. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. This ASU defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. The Company expects to adopt the new revenue standard as of January 1, 2018 using the modified retrospective method. The Company has completed its assessment of the first step which included identifying the Company's customers. Through the remainder of 2017, the Company will continue to assess the potential impact of adopting this new standard on any current, new or significantly modified customer contracts. In subsequent quarters, the Company will complete its evaluation of additional disclosures that may be required upon adoption of the new standard.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*. This ASU provides guidance about which changes to the terms or conditions of a share-based payment award requires the Company to apply modification accounting. This ASU will be effective for the Company for annual reporting periods, including interim reporting periods, beginning after December 15, 2017. Early adoption is permitted. The Company is currently assessing the potential effects of this ASU on its consolidated financial statements.

### Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. For purposes of this calculation, preferred stock, stock options, restricted stock units and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
<b>Numerator:</b>				
Net loss used to compute basic net loss per share	\$ (26,070)	\$ (18,268)	\$ (59,328)	\$ (30,465)
Less: Gain on private placement warrants	(4,246)	-	-	-
Net loss used to compute diluted net loss per share	\$ (30,316)	\$ (18,268)	\$ (59,328)	\$ (30,465)
<b>Denominator:</b>				
Weighted-average shares used to compute basic net loss per share	38,072,763	20,899,297	36,905,802	19,648,792
Add: Private placement warrant shares	1,019,516	-	-	-
Weighted-average shares used to compute diluted net loss per share	39,092,279	20,899,297	36,905,802	19,648,792
<b>Net loss per share:</b>				
Basic	\$ (0.68)	\$ (0.87)	\$ (1.61)	\$ (1.55)
Diluted	\$ (0.78)	\$ (0.87)	\$ (1.61)	\$ (1.55)

For the three-month and six-month periods ended June 30, 2017 and 2016, potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported. The following potentially dilutive securities have been excluded from diluted net loss per share, because their effect would be antidilutive, as of June 30, 2017 and 2016:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Options to purchase common stock	4,594,682	2,996,038	4,594,682	2,996,038
Restricted stock units	814,627	547,486	814,627	547,486
Warrants to purchase common stock	17,514	2,030,023	1,231,659	2,030,023

### 3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amount of certain financial instruments, including cash and cash equivalents, contracts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that

would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

*Level 1* : Quoted prices in active markets for identical assets or liabilities.

*Level 2* : Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

*Level 3* : Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Where quoted prices are available in an active market, securities are classified as Level 1 of the valuation hierarchy. The Company's Level 2 valuations of marketable securities are generally derived from independent pricing services based upon quoted prices in active markets for similar securities, with prices adjusted for yield and number of days to maturity, or based on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets.

In certain cases, where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy. Level 3 liabilities that are measured at estimated fair value on a recurring basis consist of a derivative liability in connection with loan payable and a warrant liability in connection with the Private Placement.

As of June 30, 2017 and December 31, 2016, financial assets and liabilities measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above were as follows (in thousands):

	June 30, 2017			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Assets</b>				
Cash	\$ 117,701	\$ —	\$ —	\$ 117,701
<b>Level 1:</b>				
Restricted cash	12,566	—	—	12,566
Money market funds	11,300	—	—	11,300
Subtotal	23,866	—	—	23,866
<b>Level 2:</b>				
Corporate debt securities	20,869	—	(8)	20,861
U.S. Treasury bills	35,017	—	(34)	34,983
Commercial paper	45,449	—	—	45,449
Subtotal	101,335	—	(42)	101,293
Total	\$ 242,902	\$ —	\$ (42)	\$ 242,860
<b>Reported as:</b>				
Cash and cash equivalents				\$ 143,999
Short-term investments				\$ 86,295
Restricted cash				\$ 12,566
<b>Liabilities, Level 3</b>				
Warrant Liability				\$ 23,043
Derivative Liability				\$ 642
Total				\$ 23,685

	December 31, 2016			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>Assets</b>				
Cash	\$ 3,728	\$ —	\$ —	\$ 3,728
<b>Level 1:</b>				
Restricted cash	377	—	—	377
Money market funds	115,236	—	—	115,236
Subtotal	115,613	—	—	115,613
<b>Level 2:</b>				
Corporate debt securities	12,969	—	(7)	12,962
Commercial paper	13,950	—	—	13,950
Subtotal	26,919	—	(7)	26,912
Total	\$ 146,260	\$ —	\$ (7)	\$ 146,253
Reported as:				
Cash and cash equivalents				\$ 118,964
Short-term investments				\$ 26,912
Restricted cash				\$ 377
<b>Liabilities, Level 3</b>				
Warrant liability				\$ 13,874
Derivative liability				\$ 602
Total				\$ 14,476

All available-for-sale securities held as of June 30, 2017 had maturities less than one year from the date of acquisition. There were no sales of available-for-sale securities in any of the periods presented. The carrying value of debt securities that were in unrealized loss positions totaled \$54.1 million as of June 30, 2017. The Company has determined that (i) it does not have the intent to sell any of these investments, and (ii) it is not more likely than not that it will be required to sell any of these investments before recovery of the entire amortized cost basis. The Company anticipates that it will recover the entire amortized cost basis of such debt securities and has determined that no other-than-temporary impairments associated with credit losses were required to be recognized during the three-month and six-month periods ended June 30, 2017.

Pursuant to the loan and security agreement with Solar Capital Ltd. (see Note 7), the Company entered into a Success Fee Agreement under which the Company agreed to pay \$1.0 million in cash (the "Success Fee") if the Company obtains approval to market plazomicin from the Food and Drug Administration (the "FDA"). If such approval is obtained, the Success Fee shall be due the later of (i) August 5, 2019 or (ii) the date such FDA approval is obtained. The fair value of the Success Fee, approximately \$602,000 at December 31, 2016, is recorded as a derivative liability and included in other long-term liabilities on the accompanying condensed consolidated balance sheet. The estimated fair value of the derivative liability as of June 30, 2017 increased by \$40,000 to \$642,000 from December 31, 2016, as a result of the time value of money, which is presented as change in warrant and derivative liabilities in the Company's condensed consolidated statements of operations for the six-month period ended June 30, 2017.

The fair value of the derivative liability was determined using a discounted cash flow analysis, and is classified as a Level 3 measurement within the fair value hierarchy since the Company's valuation utilized significant unobservable inputs. Specifically, the key assumptions included in the calculation of the estimated fair value of the derivative instrument include: i) the Company's estimates of both the probability and timing of a potential \$1.0 million payment to Solar Capital Ltd. upon FDA approval to market plazomicin, and ii) a discount rate of 13% which was derived from the Company's estimated cost of debt. The estimated fair value of the derivative liability is most sensitive to the probability of FDA approval. Should the probability of FDA approval change by 5%, the fair value of the derivative liability as of June 30, 2017 would change by approximately \$38,000. For the three-month and six-month periods ended June 30, 2017, there was no change to the key assumptions used in the calculation of the estimated fair value. Any changes in the estimated fair values are presented as changes in warrant and derivative liabilities in the Company's condensed consolidated statements of operations.

Pursuant to the Private Placement (see Note 2), the Company issued warrants to purchase 1,999,999 shares of common stock at an exercise price of \$3.66. The Company classified these warrants as a liability measured at fair value using Black-Scholes. Under certain entity conditions, the holder of a warrant may require the Company to settle the warrant in cash at its estimated fair value using Black-Scholes. On the closing date of the Private Placement, June 3, 2016, the \$2.6 million initial estimated fair value of the warrants was recorded as a warrant liability on the accompanying condensed consolidated balance sheet. At June 30, 2017 and December 31, 2016, the estimated fair values of the warrants were approximately \$23.0 million and \$13.9 million, respectively. The change in the estimated fair value is primarily due to the increase in the Company's stock price and is included in changes in warrant and derivative liabilities in the Company's condensed consolidated statements of operations.

In February 2017, certain holders of these warrants exercised warrants to purchase 78,585 shares of common stock. The Company received \$0.3 million in proceeds from these warrant exercises. The Company is required to record the exercised warrants at its estimated fair value at the time of exercise, with any change included in changes in warrant and derivative liabilities in the Company's condensed consolidated statements of operations. The Company estimated the fair value of these exercised warrants at their respective exercise dates to be \$1.5 million, an increase of \$0.7 million from its valuation, at December 31, 2016, of \$0.8 million, primarily due to an increase in the Company's stock price.

The fair value of the warrant liability is classified as a Level 3 measurement within the fair value hierarchy since the Company's valuation utilized significant unobservable inputs, including the risk-free interest rate, expected share price volatility, underlying price per share of the Company's common stock and remaining term of the warrants. At June 30, 2017 and December 31, 2016, the estimated fair values of the warrants were determined using Black-Scholes with the following assumptions:

	June 30, 2017	December 31, 2016
Expected volatility	80%	80%
Expected term	3.9 years	4.2 years
Risk-free interest rate	1.7%	1.8%
Dividend yield	—%	—%

The expected volatility is based on the Company's expected volatility. The expected term is based on the remaining life of the warrants. The risk-free interest rate is obtained from the yields on actively traded U.S. Treasury securities for a period equal to the expected term of the warrants. The dividend yield is zero because the Company has never paid cash dividends and has no present intention to pay cash dividends. Should the share price change by 5%, the fair value of the warrant liability as of June 30, 2017 would change by approximately \$1.3 million.

Changes in the fair value of recurring measurements included in Level 3 of the fair value hierarchy are presented as changes in warrant and derivative liabilities in the Company's condensed consolidated statements of operations and were as follows for the six-month period ended June 30, 2017 (in thousands):

	Estimated Fair Value of Warrant Liability	Estimated Fair Value of Derivative Liability
Balance of Level 3 Liabilities at December 31, 2016	\$ 13,874	\$ 602
Change in estimated fair value of warrant liability	10,690	—
Reclassification of warrant liability to additional paid in capital upon exercise of warrants	(1,521)	—
Change in estimated fair value of derivative liability	—	40
Balance of Level 3 Liabilities at June 30, 2017	<u>\$ 23,043</u>	<u>\$ 642</u>

Warrants outstanding as of June 30, 2017 and 2016 have a weighted-average exercise price of \$3.78

#### 4. Balance Sheet Components

##### *Prepays and other current assets*

Prepays and other current assets consisted of the following (in thousands):

	June 30, 2017	December 31, 2016
Deferred research and development costs	\$ 5,777	\$ 660
Prepaid expenses	1,860	1,390
Other current assets	173	139
	<u>\$ 7,810</u>	<u>\$ 2,189</u>

### ***Property and Equipment, net***

Property and equipment, net consisted of the following (in thousands):

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
Office equipment	\$ 836	\$ 644
Laboratory equipment	5,109	4,038
Leasehold improvements	8,127	1,072
Construction-in-progress	—	1,896
	<u>14,072</u>	<u>7,650</u>
Less: accumulated depreciation and amortization	(2,657)	(4,389)
Property and equipment, net	<u>\$ 11,415</u>	<u>\$ 3,261</u>

Depreciation and amortization expense for the three-month periods ended June 30, 2017 and 2016 was \$0.3 million and \$0.1 million, respectively, and \$0.4 million and \$0.2 million, respectively, for the six-month periods ended June 30, 2017 and 2016.

### ***Accrued Liabilities***

Accrued liabilities consisted of the following (in thousands):

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
Accrued clinical and development expenses	\$ 2,179	\$ 3,681
Payroll and related bonus expenses	3,902	4,941
Other	2,304	1,076
	<u>\$ 8,385</u>	<u>\$ 9,698</u>

## **5. License and Collaboration Agreements**

### ***Thermo Fisher Scientific, Inc.***

In April 2016, the Company entered into an agreement with its collaboration partner, Microgenics Corporation (“Thermo Fisher”), a wholly owned subsidiary of Thermo Fisher Scientific, Inc., to develop and commercialize an assay to support plazomicin. If approved, the Company and Thermo Fisher plan to have a commercial assay for plazomicin available at launch to enable health care professionals to make decisions on safe and efficacious doses of plazomicin. In accordance with the terms of the agreement, the Company is required to make milestone payments with respect to research, development, regulatory and commercialization milestones (if any). All such milestone payments may total, in aggregate, up to but no more than \$6,453,000. In further consideration of this agreement, in the event of a successful commercialization of the assay, the Company is required to pay a minimum threshold annual revenue to Thermo Fisher.

In February 2017, the Company announced the achievement of a strategic milestone in its ongoing collaboration to develop an assay enabling therapeutic drug management of plazomicin, and incurred \$915,000 of research and development expense related to this milestone. As of June 30, 2017, the Company has incurred \$1,433,000 in milestone payments and these costs were fully recorded as research and development expense.

### ***Crystal Biosciences, Inc.***

In May 2016, the Company entered into a collaboration and license agreement with Crystal Biosciences, Inc. (“Crystal”). Pursuant to the terms of this agreement, the Company and Crystal agreed to collaborate on the discovery of monoclonal antibodies against multiple targets. Crystal agreed to conduct the initial discovery work with its antibody platform and the Company has the right to develop and commercialize the antibodies discovered through this collaboration. The Company is required to provide signing and milestone payments with respect to research, development, regulatory and commercialization milestones (if any). All such milestone payments may total, in aggregate, up to but no more than \$20,550,000. The upfront signing fee, technology access fees and research funding were recorded as research and development expense. This collaboration and license agreement also provides that the Company shall pay royalties equal to a low single-digit percentage of annual worldwide net sales of the commercialized product.

### ***Ionis Pharmaceuticals***

In January 2006, the Company entered into a license agreement with Ionis Pharmaceuticals, Inc. (“Ionis”). Ionis granted the Company an exclusive, worldwide license with the right to grant and authorize sublicenses related to the research and development of aminoglycoside products. As an up-front fee, the Company issued 97,402 shares of Series A convertible preferred stock at a fair value

of \$15.40 per share. This license fee of \$1,500,000 was recorded as research and development expense in 2006. In further consideration of this license, and in accordance with the terms of the agreement, the Company is required to make milestone payments with respect to development, regulatory and commercialization milestones, and to pay a percentage of revenue received from sublicensees (if any). All such milestone and sublicense revenue payments may total, in the aggregate, up to but no more than \$19,500,000 for the first product and \$9,750,000 following the second product commercialized under the agreement with Ionis. The Company is also required to pay additional milestone payments of up to \$20,000,000 in the aggregate upon the first achievement of specified threshold levels of annual net sales of all aminoglycoside products in a calendar year. The license agreement also provides that the Company shall pay royalties equal to a low single-digit percentage of annual worldwide net sales of all licensed products, including, if applicable, plazomicin.

Through June 30, 2017, the Company had compensated Ionis \$7,000,000 in connection with the first three milestones under the license for the first aminoglycoside product candidate. As of June 30, 2017, the Company had no outstanding payments due under the agreement.

## **6. Revenue Contracts**

Certain of the Company's drug discovery and development activities are performed under contracts with the Gates Foundation and U.S. government agencies. Management has determined that the Company is the principal participant in the following contract arrangements, and, accordingly, the Company records amounts earned under the arrangements as revenue. Costs incurred under the Revenue Contracts are recorded as operating expenses in the Company's consolidated statements of operations.

### ***Bill & Melinda Gates Foundation***

In May 2017, the Company entered into an agreement with the Gates Foundation to discover drug candidates against gram-negative bacterial pathogens intended to prevent neonatal sepsis (the "Grant Agreement"). The Gates Foundation awarded the Company up to approximately \$10.5 million in grant funding ("Grant Funds") over a three-year research term, of which approximately \$3.2 million of committed funding was received in May 2017 (the "Advance Funds"). The Advance Funds are replenished by the Gates Foundation each calendar year, or sooner, following the Company's submission of a progress report, including expenses incurred for the research activities. Under certain conditions, as described in the Grant Agreement, the Gates Foundation may terminate the Grant Agreement and the Company is obligated to return to the Gates Foundation any unused portion of the Advance Funds. In accordance with the Company's significant accounting policies, the Advance Funds are recorded as deferred revenue.

The Company recorded contract revenue of \$206,000 under this agreement during the three-month and six-month period ended June 30, 2017. The Company did not record any contract revenue from the Gates Foundation during 2016.

### ***Biomedical Advanced Research and Development Authority***

In August 2010, the Company was awarded a contract with the Biomedical Advanced Research and Development Authority ("BARDA") for the development, manufacturing, nonclinical and clinical evaluation of, and regulatory filings for, plazomicin as a countermeasure for disease caused by antibiotic-resistant pathogens and biothreats. The original contract included committed funding of \$27,600,000 for the first two years of the contract and subsequent options exercisable by BARDA to provide additional funding. In September 2012, BARDA exercised an additional \$15,798,000 contract option ("Option 1"), which increased the total contract committed funding to \$43,398,000 through March 2014. In April 2013, the Company was awarded an additional \$60,410,000 under the contract to support its Phase 3 clinical trial of plazomicin ("Option 2") to increase the total committed funding under this contract to \$103,808,000. On May 26, 2016, the Company was awarded an additional \$20 million ("Option 3") under the contract to support its Phase 3 EPIC trial of plazomicin. In April 2017, BARDA modified Option 1 to allow for an additional \$492,000 of contract funding. This brings the total committed funding under the contract to \$124,300,000.

The Company recorded contract revenue of \$609,000 and \$8,510,000 under this agreement during the three-month periods ended June 30, 2017 and 2016, respectively, and \$7,723,000 and \$13,780,000, respectively, during the six-month periods ended June 30, 2017 and 2016.

### ***National Institute of Allergy and Infectious Diseases***

In July 2015, the Company was awarded a contract by the National Institute of Allergy and Infectious Diseases ("NIAID") for \$1.5 million committed through June 30, 2016. In January 2016, an additional committed funding of \$0.5 million was added. In April 2016, NIAID modified the contract to exercise the first option to increase the total contract committed funding to \$4.4 million through February 2018. In April 2017, NIAID modified the contract to add committed funding of \$0.3 million to the first option, bringing the total committed funding to \$4.7 million. In June 2017, NIAID modified the contract to exercise the second option of \$0.6 million, bringing the total committed funding to \$5.3 million.

The Company recorded contract revenue of \$451,000 and \$634,000 under these agreements during the three-month periods ended June 30, 2017 and 2016, respectively, and \$800,000 and \$1,213,000, respectively, during the six-month periods ended June 30, 2017 and 2016.

## 7. Borrowings

### *Solar Capital Ltd. Loan Agreement*

On August 5, 2015, the Company entered into a loan and security agreement (the “Loan Agreement”) with Solar Capital Ltd. (the “Lender”) pursuant to which the Lender agreed to make available to the Company term loans in an aggregate principal amount of up to \$25.0 million with a maturity date of August 5, 2019. An initial \$15.0 million term loan was funded at closing on August 5, 2015, and a second \$10.0 million term loan was funded on June 20, 2016. Borrowings under the term loans bear interest per annum at 6.99% plus the greater of 1% or the one-month LIBOR. The Company is currently required to make interest-only payments on the term loans through August 2017, and beginning on September 1, 2017 the Company is required to make monthly payments of interest plus equal monthly payments of principal over a term of 24 months. The Loan Agreement requires collateral by a security interest in all of the Company’s assets except intellectual property (which is subject to a negative pledge) and contains customary affirmative and negative covenants, and also includes standard events of default, including payment defaults. Upon the occurrence of an event of default, a default interest rate of an additional 4% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. There were no financial covenants attached to the loan. The Loan Agreement included a closing fee of \$250,000 which was paid at closing, and the Company is obligated to pay a fee equal to 8% of the term loans funded upon the earliest to occur of the maturity date, the acceleration of the term loans or the voluntary prepayment of the term loans. The cost of these fees is being amortized as interest expense over the term of the loan using the effective-interest method. The Company may voluntarily prepay all, but not less than all, of the outstanding term loans. The Loan Agreement contains customary representations, warranties and covenants. In addition, the Loan Agreement contains customary events of default that entitle the Lender to cause the Company’s indebtedness under the Loan Agreement to become immediately due and payable.

On August 5, 2015, pursuant to the Loan Agreement, the Company entered into a Success Fee Agreement with the Lender under which the Company agreed to pay the Lender \$1.0 million if the Company obtains FDA approval to market plazomicin. If such approval is obtained, the Success Fee shall be due the later of (i) August 5, 2019 or (ii) the date such FDA approval is obtained. The fair value of the Success Fee at the date of issuance of approximately \$356,000 was recorded as a debt discount and is being amortized as interest expense over the term of the loan using the effective-interest method.

Future principal debt payments on the currently outstanding term loan are payable as follows (in thousands):

	<b>June 30, 2017</b>
2017	\$ 4,167
2018	12,500
2019	8,333
Total principal payments	25,000
Final fee due at maturity in 2019	2,000
Total principal and final fee payments	27,000
Unamortized discount and debt issuance costs	(1,303)
Less current portion	(10,417)
Loan payable, long-term	<u>\$ 15,280</u>

The obligation includes a final fee of \$2,000,000, representing 8% of the term loan currently funded, which accretes over the life of the loan as interest expense. The Company recorded interest expense related to the loan of \$0.7 million and \$0.4 million for the three-month periods ended June 30, 2017 and 2016, respectively, and \$1.4 million and \$0.9 million, respectively, for the six-month periods ended June 30, 2017 and 2016.

## 8. Stockholders' Equity

On April 7, 2015, the Company entered into a Sales Agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”), pursuant to which the Company may issue and sell shares of its common stock having aggregate sales proceeds of up to \$30.0 million from time to time through an ATM equity program under which Cowen acts as sales agent.

As of June 30, 2017, the Company had sold 1,105,549 shares of common stock under the Sales Agreement, at a weighted-average price of approximately \$4.82 per share for aggregate gross proceeds of \$5.3 million and net proceeds of \$5.1 million after

deducting the sales commissions and offering expenses. As of June 30, 2017, \$24.7 million of common stock remained available to be sold under the Sales Agreement, subject to certain conditions specified therein.

On June 3, 2016, the Company sold 7,999,996 shares of its common stock and warrants to purchase 1,999,999 shares of its common stock pursuant to the Purchase Agreement for aggregate gross proceeds of \$25.4 million in the Private Placement. The warrants have an exercise price of \$3.66 and are exercisable up to five years from the date of issuance. The Company's Chief Operating Officer, a related party, participated in the Private Placement by purchasing 141,453 shares of common stock and a warrant to purchase 35,363 shares of common stock for an aggregate purchase price of \$0.5 million. Issuance costs of \$0.3 million were offset against equity as a reduction from gross proceeds.

At the close of the Private Placement, the estimated fair values of the common stock and warrants issued were \$22.9 million and \$2.6 million, respectively. At June 30, 2017, using Black-Scholes, the Company estimated the fair value of the remaining warrants outstanding to be \$23.0 million and recorded a charge of \$11.3 million and \$10.7 million, for the increase in the liability, in the condensed consolidated statements of operations, for the year ended December 31, 2016 and six-month period ended June 30, 2017, respectively.

On December 19, 2016, the Company completed an underwritten public offering of 7,475,000 shares of its common stock at a price to the public of \$13.50 per share, including the full exercise of the underwriters' option to purchase an additional 975,000 shares of common stock. The Company received net proceeds from the offering of \$94.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

On May 31, 2017, the Company completed an underwritten public offering of 5,750,000 shares of its common stock at a price to the public of \$22.50 per share, including the closing of the full exercise of the underwriters' option to purchase an additional 750,000 shares of common stock on June 9, 2017. The Company received net proceeds from the offering of \$121.2 million, after deducting the underwriting discounts and commissions and offering expenses.

## **Equity Incentive Plans**

### ***2014 Equity Incentive Award Plan***

In February 2014, the Company's stockholders approved the 2014 Equity Incentive Award Plan (the "2014 Plan"), which became effective as of March 11, 2014. Under the 2014 Plan, the Company may grant incentive stock options ("ISOs"), nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units ("RSUs") and other stock-based awards for the purchase of that number of shares of common stock. Effective, January 1, 2017, the compensation committee of the board of directors approved an evergreen increase of 1,425,522 shares that may be granted in accordance with the terms of the 2014 Plan. As of June 30, 2017, 726,319 shares were available for future issuance under the 2014 Plan.

Under the 2014 Plan, the terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2014 Plan. Options granted by the Company typically vest over a four year period and the exercise price may not be less than fair market value on the date of grant. Certain of the options are subject to acceleration of vesting in the event of certain change of control transactions. Options granted under the 2014 Plan expire no later than 10 years from the date of grant.

### ***2014 Employment Commencement Incentive Plan***

In December 2014, the Company adopted a 2014 Employment Commencement Incentive Plan (the "Inducement Plan"). The Inducement Plan is designed to comply with the inducement exemption contained in Nasdaq's Rule 5635(c)(4), which provides for the grant of non-qualified stock options, RSUs, restricted stock awards, performance awards, dividend equivalents, deferred stock awards, deferred stock units, stock payment and stock appreciation rights to a person not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the Company. As of June 30, 2017, a total of 1,600,000 shares of common stock have been authorized under the Inducement Plan, including the additional 450,000 shares that became available resulting from an amendment adopted by the board of directors as of February 22, 2017. As of June 30, 2017, 283,268 shares were available for future issuance under the Inducement Plan.

### ***2014 Employee Stock Purchase Plan***

In February 2014, the Company's stockholders approved the 2014 Employee Stock Purchase Plan (the "ESPP"), which became effective as of March 11, 2014. Effective, January 1, 2017, the compensation committee of the board of directors approved an evergreen increase of 178,190 shares that may be granted in accordance with the terms of the ESPP. As of June 30, 2017, 336,139 shares of common stock have been issued to employees participating in the ESPP, and 350,528 shares are available for issuance under the ESPP.

### Amended and Restated 2003 Stock Plan

The Company's Amended and Restated 2003 Stock Plan (the "2003 Plan"), provided for the granting of incentive and non-statutory stock options to employees, directors and consultants at the discretion of the board of directors. The Company granted options under its 2003 Plan until January 2014 and it was terminated as to future awards in March 2014, although it continues to govern the terms of options that remain outstanding under the 2003 Plan.

Options granted under the 2003 Plan expire no later than 10 years from the date of grant. Options granted under the 2003 Plan vest over periods determined by the board of directors, generally over four years.

The 2003 Plan allows for early exercise of certain options prior to vesting. Upon termination of employment, the unvested shares are subject to repurchase at the original exercise price. Stock options granted or modified after March 21, 2002, that are subsequently exercised for cash prior to vesting, are not deemed to be issued until those shares vest. As of June 30, 2017 and December 31, 2016 there were no shares subject to repurchase relating to the early exercise of options.

In connection with the board of directors' and stockholders' approval of the 2014 Plan, all remaining shares available for future awards under the 2003 Plan were transferred to the 2014 Plan, and the 2003 Plan was terminated as to future awards. As of June 30, 2017, a total of 830,082 shares of common stock are subject to options outstanding under the 2003 plan, which shares will become available under the 2014 Plan to the extent the options are forfeited or lapse unexercised.

The following table summarizes stock option activity under the stock plans, excluding the ESPP, and related information:

	Shares Available for grant	Shares Subject to Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (years)
Balance, December 31, 2016	639,374	3,540,293	\$ 6.31	7.98
Additional shares authorized	1,875,522	—		
Options granted	(1,330,832)	1,330,832	\$ 22.88	
Options exercised	—	(143,781)	\$ 8.04	
Options cancelled	132,662	(132,662)	\$ 7.15	
RSUs granted	(357,681)	—		
RSUs cancelled	50,542	—		
Balance, June 30, 2017	<u>1,009,587</u>	<u>4,594,682</u>	\$ 11.03	7.86

Stock-based compensation expense recognized for stock options granted to employees and non-employee directors in the Company's condensed consolidated statements of operations was as follows (in thousands):

	Three Months Ended June 30		Six Months Ended June 30	
	2017	2016	2017	2016
Research and development	\$ 1,328	\$ 515	\$ 2,931	\$ 969
General and administrative	1,989	410	3,079	782
Total	<u>\$ 3,317</u>	<u>\$ 925</u>	<u>\$ 6,010</u>	<u>\$ 1,751</u>

Stock-based compensation expense for the six-month period ended June 30, 2017 includes \$0.6 million of expense that relate to stock options and restricted stock units held by the former Chief Medical Officer, which were modified upon his resignation in March 2017, including \$0.7 million related to such modifications.

As of June 30, 2017, approximately \$22,448,654 of total unrecognized stock-based compensation expense related to unvested stock options is expected to be recognized over a weighted-average period of 3.11 years.

The estimated grant date fair value of employee stock options with time-based vesting terms was calculated using the Black-Scholes valuation mode 1, based on the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expected term	5.3–6.0 years	5.3–6.0 years	5.3–6.0 years	5.3–6.0 years
Expected volatility	79-80%	74%	79-81%	73%–74%
Risk-free interest rate	1.7%–1.9%	1.1%–1.5%	1.7%–2.1%	1.1%–1.5%
Expected dividend yield	—%	—%	—%	—%

#### Stock Options Granted to Non-Employees

During the three-month and six-month periods ended June 30, 2017, the Company granted to a non-employee consultant an option to purchase an aggregate of 3,000 shares of common stock and 1,500 RSUs, that vest upon the achievement of certain performance-based targets. The Company will record the estimated fair value of the awards at the time the performance-based targets are met, which has not occurred as of June 30, 2017. During the three-month and six-month periods ended June 30, 2016, the Company did not grant any stock options or RSUs to non-employees. The Company recorded non-employee stock-based compensation expense of approximately \$195,000 and zero for the three-month periods ended June 30, 2017 and 2016, respectively, and \$414,000 and zero, respectively, for the six-month periods ended June 30, 2017 and 2016. The Company measures the estimated fair value of the award for each period until the award is fully vested. The non-employee stock-based compensation expense, during the three-month and six-month periods ended June 30, 2017, was estimated using Black-Scholes with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expected term	0.26 years	–	0.26–0.51 years	–
Expected volatility	48%	—%	48-77%	—%
Risk-free interest rate	0.9%	—%	0.9%	—%
Expected dividend yield	—%	—%	—%	—%

#### Restricted Stock Units Granted to Employees

During the six-month period ended June 30, 2017, the Company granted RSUs to employees to receive 357,681 shares of common stock under the Company's stock plans with a weighted-average estimated grant-date fair value of \$23.15 per share. RSUs generally vest annually over a 4-year service period and vesting is contingent on continued service. As of June 30, 2017, there were unrecognized compensation costs of \$9,260,032 related to outstanding RSUs, which are expected to be recognized over a weighted-average period of 3.25 years.

A summary of RSU activity is as follows:

	RSU Awards Outstanding		Aggregate Intrinsic Value (in thousands)
	Number of Shares	Weighted-Average Grant Date Fair Market Value	
Balance, December 31, 2016	605,052	\$ 5.60	\$ 7,878
RSUs granted	357,681	\$ 23.15	
RSUs released	(97,564)	\$ 5.06	
RSUs cancelled	(50,542)	\$ 7.12	
Balance, June 30, 2017	814,627	\$ 12.81	\$ 17,702

#### Stock Options and Restricted Stock Units Granted to Employees that Contain Performance Conditions

During the three-month periods ended June 30, 2017 and 2016, the Company granted options to purchase an aggregate of 14,500 and 11,500 shares of common stock, respectively, and 156,700 and 211,250, respectively, that vest upon the achievement of market-based common stock price targets, for the six-month periods ended June 30, 2017 and 2016. During the three-month periods ended June 30, 2017 and 2016, the Company granted 3,150 and 2,750 RSUs, respectively, and 28,950 and 50,175 RSUs, respectively, that vest upon the achievement of market-based common stock price targets, for the six-month periods ended June 30, 2017 and 2016.

The fair value was estimated at the grant date using a Monte-Carlo simulation model (“Monte-Carlo”), which requires the use of a range of assumptions. The expected life assumption is not used in Monte-Carlo, but the output of the model indicates an expected

term. The associated stock-based compensation expense is being recognized on a straight-line basis over the implicit service period (expected time to vest) derived from Monte-Carlo. The fair value of awards granted to employees was estimated using Monte-Carlo with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expected term	0.5–1.8 years	2.5–5.7 years	0.5–1.8 years	2.5–6.0 years
Expected volatility	75%	70%	75%	70%
Risk-free interest rate	2.4%	1.7%	2.4%	1.7%
Expected dividend yield	—%	—%	—%	—%

## 9. Contingently Redeemable Common Stock

In May 2017, the Company entered into a Common Stock Purchase Agreement with the Gates Foundation, pursuant to which the Company agreed to sell 407,331 shares of its contingently redeemable common stock (the “Shares”) to the Gates Foundation in a private placement at a purchase price per share equal to \$24.55, for gross proceeds to the Company of \$10.0 million (“Gates Investment”).

In connection with the Gates Investment, the Company entered into the Letter Agreement, which includes terms of Global Access Commitments (see Note 1). Under the Letter Agreement, if the Company defaults in its obligation to conduct certain mutually-agreed upon work with the proceeds from the Gates Investment, or otherwise triggers certain other events of default (“Charitable Default”), subject to a cure period, the Gates Foundation will have the right to request that (a) the Company redeem, or facilitate the purchase by a third party of, the Shares then held by the Gates Foundation at a price per share equal to the greater of (i) the fair market value of the common stock (if the Shares are freely tradable, the closing price of the Company’s common stock on the trading day prior to the redemption or purchase, as applicable), or (ii) an amount equal to \$24.55 plus a compounded annual return of 5% from the date of issuance of the Shares, or (b) if the Shares then held by the Gates Foundation are not freely tradeable, the Company register the resale of the Shares held by the Gates Foundation on an effective registration statement, subject to certain conditions and qualifications.

The Company concluded that certain potential events of the Charitable Default, as defined in the agreement, are not solely within the control of the Company and, accordingly, has classified the Shares outside of permanent equity, as temporary equity (the “Mezzanine Equity”). The 407,331 shares classified as Mezzanine Equity were recorded as contingently redeemable common stock at an initial carrying value equal to the gross proceeds of approximately \$10 million, which approximated their fair value at the date of issuance. The Company has determined that the 407,331 shares of contingently redeemable common stock are not currently redeemable and that a Charitable Default is not currently probable. If, and at the time when, a Charitable Default becomes probable, then the Company will record a change in the carrying value to adjust it to the redemption value of the contingently redeemable common stock. At the time of such an occurrence, the contingently redeemable common stock will be adjusted to equal the redemption value at the end of each reporting period.

## 10. Commitments

### *Commercial Manufacturing Agreement*

In March 2017, the Company entered into a commercial validation and manufacturing agreement (the “Manufacturing Agreement”) with Hovione Limited (“Hovione”). Under the Manufacturing Agreement, Hovione has agreed to complete the validation program to validate and scale up the Company’s technology to manufacture the active pharmaceutical ingredient for plazomicin (the “Product”) and supply the Product to the Company. The Manufacturing Agreement has an initial term of seven years after the first delivery of the Product.

Subject to the successful completion of the validation program and the Company’s launch of plazomicin, the Company has agreed to purchase a minimum quantity of the Product from Hovione depending on the Company’s requirements and the period of time following approval by the FDA. For the first three years following approval of plazomicin by the FDA, the Company is required to purchase at least 80% of its required quantity from Hovione. Following the initial three years after FDA approval, the Company is required to purchase between 40% and 66% of its required quantity from Hovione, depending on the amounts required during any such fiscal year. Contingent upon FDA’s approval of plazomicin, the Company has minimum annual purchase commitments from Hovione, beginning in 2020 through 2024.

In connection with the Manufacturing Agreement, the Company executed certain work plans to carry out the validation and commercial manufacturing of plazomicin (the “Work Plans”). The Work Plans obligate the Company to make an aggregate amount of

approximately \$6.2 million in nonrefundable advance payments, of which \$1.5 million was for the reservation of facilities and resources, plus procurement of long lead raw materials, paid in full under a separate agreement executed in July 2015. Such advance payments are initially capitalized as prepaid and other current assets and will be recognized as research and development expenses as goods are delivered and/or services are performed. The Company assesses such prepaid and other current assets for impairment if events or changes in circumstances indicate that the carrying amount may not be recoverable or may not provide future economic benefits. Further, the Work Plans include certain terms that require the Company to compensate Hovione if it chooses to cancel the Work Plans ("Cancellation Clause"). As of June 30, 2017, \$9.8 million is committed under the Cancellation Clause and the total aggregate amount of potential commitments, if all the services are rendered by Hovione, is approximately \$28.1 million. As of June 30, 2017 and December 31, 2016, the Company has recorded approximately \$4.6 million and \$0.7 million, respectively as prepaid and other current assets and, during the three-month periods ended June 30, 2017 and 2016, has recognized \$1.2 million and \$0.4 million, respectively, and \$1.6 million and \$0.4 million, respectively, during the six-month periods ended June 30, 2017 and 2016, as research and development expenses, related to the Work Plans.

In December 2016, the Company entered into an agreement with Hovione to procure certain long lead raw materials to be used in the commercial production of plazomicin (the "Raw Material Agreement"). The Raw Material Agreement includes \$1.2 million in nonrefundable advance payments. As of June 30, 2017, the Company has recorded \$1.2 million of these nonrefundable advance payments as prepaid and other current assets.

#### ***Facilities Lease Obligation***

The Company leased its former principal executive offices in South San Francisco under a non-cancelable lease agreement that expired on April 14, 2017. In August 2016, the Company entered into a non-cancelable agreement (the "Lease") to lease approximately 47,000 square feet of office, laboratory and research and development space for the Company's new principal executive offices ("Premises") in South San Francisco. The Lease commenced in March 2017, after the substantial completion of certain improvements ("Tenant Improvements") required under the Lease, set to expire in September 2027 ("Lease Term"), and the Company moved into the Premises in April 2017. The Lease contains expansion options and an option to extend the Lease Term for an additional 5 years. Base rent for the first year of the Lease Term is approximately \$2.7 million, with an increase in annual base rent of approximately 3.5% in each subsequent year of the Lease Term. The Lease also provides for rent abatement of approximately \$1.8 million for the first year of the Lease Term.

The Company has a one-time improvement allowance of \$5.7 million for the Tenant Improvements (the "Allowance"). The Landlord disbursed the Allowance for the Tenant Improvement on behalf of the Company. As of June 30, 2017, the Company has recorded approximately \$5.7 million within leasehold improvements under property, plant and equipment, net and other current liabilities in the condensed consolidated balance sheet related to costs incurred under the Allowance. At its election, the Company is also entitled to an additional improvements allowance of \$0.9 million ("Additional Allowance"). In the event the Company elects to use the Additional Allowance, the base rent will be increased as calculated in the Lease. Further, the Company had a deposit of \$250,000 included in long-term restricted cash as of June 30, 2017, restricted from withdrawal and held in a money market account with one of the Company's financial institutions in the form of collateral for a letter of credit held as security for the Lease. In July 2017, the Company executed a lease amendment to the Lease for additional space at the Premises and to extend the Lease Term through January 2028 (see Note 11).

Future minimum lease payments under the operating leases as of June 30, 2017 are as follows (in thousands):

Year Ending December 31,	<u>Amounts</u>	
2017	\$	508
2018		2,395
2019		2,890
2020		2,991
2021		3,098
Thereafter		20,036
<b>Total minimum lease payments</b>	<b>\$</b>	<b><u>31,918</u></b>

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Rent expense was \$0.8 million and \$0.1 million for the three-month periods ended June 30, 2017 and 2016, respectively, and \$1.0 million and \$0.3 million, respectively, for the six-month periods ended June 30, 2017 and 2016.

#### **11. Subsequent Events**

##### ***Facilities Lease Obligation***

Effective as of July 20, 2017, the Company entered into a non-cancelable amendment to the Lease (the "Lease Amendment") to lease an additional 51,866 square feet of office, laboratory and research and development space at the Premises for the expansion of the Company's principal executive offices. The lease for 18,888 square feet of space is expected to begin by the third quarter of 2017 and the remainder in the second quarter of 2018, respectively. The lease term is through January 31, 2028 and includes an option to extend for an additional 5 years. The Lease Amendment includes a requirement to obtain a standby letter of credit in the amount of \$280,000 held as security for the lease and provides for additional rent abatement and tenant improvement allowances.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2016.*

*In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II – Other Information, Item 1A. Risk Factors below and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.*

### Overview

We are a late-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel antibacterial treatments against multi-drug resistant ("MDR") gram-negative infections. We are researching and developing plazomicin, our lead product candidate, for the treatment of serious bacterial infections, including complicated urinary tract infection ("cUTI"), blood stream infections and other infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae ("CRE"). In 2013, the Centers for Disease Control and Prevention identified CRE as a "nightmare bacteria" and an immediate public health threat that requires "urgent and aggressive action" and in 2017 the World Health Organization identified CRE as a Global Priority 1 Pathogen: Critical Need for Research and Development of New Antibiotics.

On December 12, 2016, we announced positive data from our two Phase 3 clinical trials for plazomicin. The first study, a Phase 3 trial of plazomicin for the treatment of patients with cUTI and acute pyelonephritis ("AP"), entitled EPIC (Evaluating Plazomicin In cUTI), is expected to serve as a single pivotal study supporting a new drug application ("NDA") for plazomicin in the United States. The Phase 3 EPIC trial is a randomized, double blind, active controlled study in patients with cUTI and AP and allowed broad enrollment of patients with gram-negative infections. We reached agreement with the U.S. Food and Drug Administration ("FDA") that this trial comparing plazomicin to meropenem with a 15% non-inferiority margin is acceptable as the single study required for potential approval. The first patient was enrolled in the Phase 3 EPIC trial in January 2016 and enrollment was closed in August 2016 with 609 patients.

In the EPIC trial, plazomicin successfully met or exceeded the objective of non-inferiority compared to meropenem for the FDA-specified primary efficacy endpoints, and achieved superiority for the primary efficacy endpoints specified by the European Medicines Agency ("EMA"). Results for the FDA pre-specified composite endpoint of clinical cure and microbiological eradication in the microbiological modified intent-to-treat ("mMITT") population at Day 5 achieved statistical non-inferiority, and Test-of-Cure (Day ~17) achieved statistical superiority. Results for EMA-specified endpoints of microbiological eradication at the test-of-cure visit achieved statistical superiority in both the mMITT and microbiologically evaluable ("ME") populations.

Plazomicin was generally well tolerated with no new safety concerns identified in the EPIC trial. As previously disclosed, total treatment emergent adverse events ("TEAEs") related to renal function were reported in 3.6% and 1.3% of patients in the plazomicin and meropenem groups, respectively. TEAEs related to cochlear or vestibular function were reported in a single patient in each of the plazomicin and meropenem treatment groups. Both events were considered mild and resolved completely.

The second study, our Phase 3 CARE (Combating Antibiotic Resistant Enterobacteriaceae) trial was a resistant pathogen trial designed to evaluate the efficacy and safety of plazomicin in patients with serious bacterial infections due to CRE. We closed enrollment in the CARE study in August 2016 with 69 patients, comprised of 39 patients enrolled in Cohort 1, comparing plazomicin to colistin-based therapy in patients with bloodstream infections or pneumonia due to CRE, and 30 patients in Cohort 2, a single arm cohort of plazomicin treatment in patients with serious infections due to CRE. In Cohort 1 of the CARE trial, a lower rate of mortality or serious disease-related complications was observed for plazomicin compared with colistin therapy.

The safety profile of plazomicin was favorable to that of colistin in critically ill patients in the CARE trial. As previously disclosed, study drug-related TEAEs related to renal function were reported in 16.7% and 38.1% of patients in the plazomicin and colistin groups, respectively. No TEAEs related to cochlear or vestibular function were reported in either group. However, due to the clinical status of patients enrolled in the trial who were frequently ventilated and unconscious, planned assessments of hearing and tinnitus were not possible for many of the patients.

We plan to submit an NDA, which will include data from both the EPIC and CARE Phase 3 clinical trials, to the FDA in the second half of 2017, with a planned commercial launch of plazomicin in the United States in 2018, if our NDA is approved. We also plan to submit a Marketing Authorization Application to the EMA for plazomicin in 2018.

On May 23, 2017, we announced that, based on the results of the CARE study, the FDA granted Breakthrough Therapy designation for plazomicin for the treatment of bloodstream infections caused by certain Enterobacteriaceae, *Klebsiella pneumoniae* and *Enterobacter aerogenes*. Breakthrough Therapy designation is granted by the FDA to treat a serious condition and where preliminary clinical evidence demonstrates the drug may have substantial improvement on one or more clinically significant endpoints over available therapy. Breakthrough Therapy is intended to expedite the development and review of new therapies to treat such conditions. In 2012, the FDA granted fast-track designation for the development and regulatory review of plazomicin to treat serious and life-threatening CRE infections. In 2014, plazomicin received Qualified Infectious Disease Product (“QIDP”) designation from the FDA. The QIDP designation was created by the Generating Antibiotic Incentives Now (“GAIN”) Act, which was part of the FDA Safety and Innovation Act and provides certain incentives for the development of new antibiotics, including priority review and an additional five years of market exclusivity. We have global commercialization rights to plazomicin, which has patent protection in the United States estimated from 2030 to 2032.

We recently announced our orally-available antibacterial candidate, C-Scape, a combination of an approved  $\beta$ -lactam and an approved  $\beta$ -lactamase inhibitor. We believe that C-Scape has the potential to rapidly address a serious unmet need for an effective oral treatment for patients with cUTI, including AP, caused by ESBL-producing Enterobacteriaceae. We began a Phase 1 study in the second quarter of 2017. In the event the Phase 1 trial is successful, we intend to initiate a single pivotal Phase 3 study in patients with cUTI, including AP, who are suitable for treatment with oral antibiotics, by the first half of 2018. We also have a program to discover and develop small molecule inhibitors of LpxC (an enzyme essential for the synthesis of the outer membrane of gram-negative bacteria), which could be ready to file an investigational new drug application (“IND”) as early as 2018. Our LpxC program is funded in part with an award from the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) of \$3.2 million, with potential funding of up to \$11.4 million, and a contract from the National Institute of Allergy and Infectious Diseases for up to \$5.3 million. Our therapeutic antibody program utilizes a built-for-purpose discovery platform to identify and develop monoclonal antibodies for the treatment of MDR bacterial infections and other significant unmet medical needs. To further support that program, we entered into a research agreement with the Bill & Melinda Gates Foundation (the “Gates Foundation”) to discover drug candidates against gram-negative bacterial pathogens intended to prevent neonatal sepsis (the “Grant Agreement”). Pursuant to the Grant Agreement, the Gates Foundation awarded up to \$10.5 million in grant funding over a three-year research term. We have other programs in early stages of research targeting MDR gram-negative bacterial infections.

Since our inception, we have financed our operations with the proceeds from our initial public offering (“IPO”) of our common stock, proceeds from the underwritten public offering of our common stock, proceeds from sales of our common stock through the use of our at-the-market (“ATM”) equity offering program, funding under our contracts with a non-profit foundation and government agencies, private placements of our equity securities and certain debt-related financing arrangements.

Our plazomicin program is funded in part with a contract from BARDA. Our other programs are currently funded primarily with company funds, although, in 2015, we received a contract from the National Institute of Allergy and Infectious Diseases (“NIAID”) that has total committed funding of \$5.3 million. Historically, our preclinical programs have received funding support from organizations in addition to the National Institutes of Health, such as the U.S. Department of Defense and The Wellcome Trust, a global charitable foundation. We intend to continue to seek further collaborations with government agencies, non-profit foundations, and other research and development funding organizations to support our discovery efforts and advance the product candidates in our pipeline.

On March 17, 2014, we completed our IPO of common stock. We sold 6,900,000 shares of our common stock, which included 900,000 shares issued as a result of the underwriters exercising their over-allotment option in full. We received cash proceeds of approximately \$73.9 million from the IPO, net of underwriting commissions and related expenses.

On April 7, 2015, we entered into the Sales Agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”), pursuant to which we may issue and sell shares of our common stock having aggregate sales proceeds of up to \$30.0 million from time to time through an ATM equity offering program under which Cowen acts as sales agent. As of June 30, 2017, we had sold 1,105,549 shares under the Sales Agreement at an average price of \$4.82 per share and we received aggregate cash proceeds of \$5.1 million, after deducting the sales commissions and offering expenses.

On August 5, 2015, we entered into a loan and security agreement with Solar Capital Ltd., pursuant to which Solar Capital Ltd. agreed to make available to us term loans with an aggregate principal amount of up to \$25.0 million, \$15.0 million of which was provided to us on August 5, 2015 and \$10.0 million of which was provided to us on June 20, 2016.

On May 26, 2016, BARDA exercised an additional option (“Option 3”) under its existing contract, and we were awarded an additional \$20.0 million in contract funding. Option 3 also includes a no-cost extension of the period of performance for Option 1 to

September 20, 2016, under the contract to support our Phase 3 EPIC trial of plazomicin. The funding from Option 3 is focused on the Phase 3 pivotal clinical trial of plazomicin, the EPIC study, in cUTI. In April 2017, BARDA modified Option 1 to allow for an additional \$0.5 million of contract funding. This brings the total committed funding under the contract to \$124.3 million.

On June 3, 2016, we sold 7,999,996 shares of common stock and warrants to purchase 1,999,999 shares of common stock pursuant to a Securities Purchase Agreement (“Purchase Agreement”) for aggregate gross proceeds of \$25.4 million and aggregate net proceeds of \$25.1 million, after deducting the issuance costs, in a private placement financing transaction (the “Private Placement”). The warrants have an exercise price of \$3.66 and are exercisable up to five years from the date of issuance.

On December 19, 2016, we completed an underwritten public offering of common stock, which resulted in the sale of 7,475,000 shares, at a price of \$13.50 per share to the public, including the full exercise of the underwriters’ option to purchase an additional 975,000 shares of common stock. We received net proceeds from the offering of \$94.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses.

On May 4, 2017, we entered into the Grant Agreement with the Gates Foundation and were awarded up to approximately \$10.5 million in grant funding over a three-year research term, of which approximately \$3.2 million of committed funding was received in May 2017 (the “Advance Funds”). Concurrently with the Grant Agreement, we entered into a Common Stock Purchase Agreement with the Gates Foundation, pursuant to which we agreed to sell 407,331 shares of our contingently redeemable common stock to the Gates Foundation in a private placement at a purchase price per share equal to \$24.55, for gross proceeds to us of \$10.0 million (“Gates Investment”). In connection with the Grant Agreement and Gates Investment, we entered into a strategic relationship with the Gates Foundation (the “Letter Agreement”). Under the terms of the Letter Agreement, the Gates Investment and Advance Funds may only be used to conduct mutually agreed upon work, including the scale up of our antibody platform technology to launch a product intended to prevent neonatal sepsis (the “NSP”). Pursuant to the Letter Agreement, we agreed to make the NSP available and accessible in certain developing countries and to grant the Gates Foundation a non-exclusive license to commercialize selected drug candidates in certain developing countries, which may only be exercised in the event of certain defaults as described in the Letter Agreement (the “Global Access Commitments”). The Global Access Commitments will continue in effect until the earlier of 25 years from the closing of the Gates Investment or 7 years following the termination of all funding provided by the Gates Foundation; provided, that the Global Access Commitments will continue for any products or services developed with funding provided by the Gates Foundation which continue to be developed or available in certain developing countries.

On May 31, 2017, we completed an underwritten public offering of 5,750,000 shares of its common stock at a price to the public of \$22.50 per share, including the closing of the full exercise of the underwriters’ option to purchase an additional 750,000 shares of common stock on June 9, 2017. We received net proceeds from the offering of \$121.2 million, after deducting the underwriting discounts and commissions and offering expenses.

We have never been profitable and have incurred net losses in each year since the commencement of our operations. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and associated general and administrative costs. We expect to incur substantial losses from operations in the foreseeable future as we advance plazomicin and other product candidates through preclinical and clinical development, seek regulatory approval, and prepare for, if approved, commercialization. Management expects that, based on its current operating plans, our existing cash, cash equivalents and short-term investments, will be sufficient to fund our current planned operations for at least the next twelve months from the issuance of these financial statements. We will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources to invest in the commercial launch of plazomicin and continued progress with our research and development efforts. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We perform all of our manufacturing in conjunction with third parties. Additionally, we currently utilize third-party clinical research organizations (“CROs”) to carry out our clinical development and are building a sales organization. We will need substantial additional funding to support our operating activities and adequate funding may not be available to us on acceptable terms, or at all.

## **Financial Overview**

### ***Contract Revenue***

We have derived all of our revenue to date from funding provided under a non-profit foundation and U.S. government contracts (collectively, the “Revenue Contracts”) in connection with the development of our product candidates. Our product candidates are still in clinical and preclinical development and may never be successfully developed or commercialized. Other than this contract revenue from the Revenue Contracts, we do not expect to derive any revenue from any product candidates that we develop until we obtain regulatory approval and commercialize such products, which we do not expect will occur before 2018, if at all, or until such time that we potentially enter into collaboration agreements with third parties for the development and commercialization of such product candidates.

**Bill & Melinda Gates Foundation.** In May 2017, we entered into an agreement with the Gates Foundation to discover drug candidates against gram-negative bacterial pathogens intended to prevent neonatal sepsis. The Gates Foundation awarded up to approximately \$10.5 million in grant funding over a three-year research term, of which approximately \$3.2 million of funding was received in May 2017.

For the three-month and six-month periods ended June 30, 2017, total revenue recognized under the Gates Foundation contract was \$0.2 million. We did not recognize any revenue from the Gates Foundation in 2016.

**Biomedical Advanced Research and Development Authority (BARDA)** . We have received funding for our lead product candidate, plazomicin, under a contract with BARDA, an agency of the U.S. Department of Health and Human Services, for the development, manufacturing, nonclinical and clinical evaluation of, and regulatory filings for, plazomicin as a countermeasure for disease caused by antibiotic-resistant pathogens and biothreats. Our BARDA contract provides for payments to us based on direct costs incurred and allowances for overhead, plus a fee, where applicable. The total committed funding under our BARDA contract is \$124.3 million, including \$20.0 million for Option 3, exercised by BARDA on May 26, 2016. The exercised option relates to the support of our Phase 3 EPIC study and the preparation and submission of an NDA to the FDA. In addition, in April 2017, BARDA modified Option 1 to allow for an additional \$0.5 million of contract funding.

For the three-month periods ended June 30, 2017 and 2016, total revenue recognized under the BARDA contract was \$0.6 million and \$8.5 million, respectively, and \$7.7 million and \$13.8 million, respectively, for the six-month periods ended June 30, 2017 and 2016. Through June 30, 2017, a total of \$124.3 million under the BARDA contract was recorded as revenue.

**National Institute of Allergy and Infectious Diseases (NIAID).** In July 2014, the Company was awarded a one-year, \$0.4 million grant by NIAID to conduct discovery research on novel antibiotics targeting gram-negative bacteria. The contract was subsequently modified to extend through July 31, 2016.

In July 2015, we were awarded a contract by NIAID for \$1.5 million committed through June 30, 2016. In January 2016, an additional committed funding of \$0.5 million was added. In April 2016, NIAID modified the contract to exercise the first option to increase the total contract committed funding to \$4.4 million through February 2018. In April 2017, NIAID modified the contract to add committed funding of \$0.3 million to the first option, bringing the total committed funding to \$4.7 million. In June 2017, NIAID modified the contract to exercise the second option of \$0.6 million, bringing the total committed funding to \$5.3 million.

For the three-month periods ended June 30, 2017 and 2016, total revenue recognized under the NIAID contracts was \$0.5 million million and \$0.6 million, respectively, and \$0.8 million and \$1.2 million, respectively, for the six-month periods ended June 30, 2017 and 2016.

### **Research and Development Expenses**

Research and development expenses consist primarily of costs associated with research, discovery and preclinical studies of potential new drug compounds, plus product development efforts related to clinical trials and materials manufacturing processes. Research and development costs are expensed as incurred and include the following:

- expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct our clinical trials and a substantial portion of our preclinical activities;
- employee and consultant-related expenses, which include salaries, benefits, stock-based compensation and consulting fees;
- third-party supplier expenses including the cost of acquiring and manufacturing clinical trial and other materials; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, amortization or depreciation of leasehold improvements, equipment and laboratory supplies and other expenses.

Advance payments for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses and recognized as an expense as the goods are delivered or the related services are performed.

We expect to continue to incur substantial expenses for the foreseeable future related to our research and development activities as we continue research programs and the development of our product candidates. Further, we have incurred substantial research and development costs associated with our plazomicin program as our Phase 3 EPIC and CARE trials have completed patient enrollment. We expect to continue to incur substantial research and development expenses in the future as we continue to support plazomicin and C-Scape development, including preparations to submit an NDA for plazomicin to the FDA.

## General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development. We anticipate general and administrative expenses will continue to increase in future periods, reflecting an expanding infrastructure in preparation for commercialization of plazomicin, if approved.

## Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial statements and in Note 2 to our audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2016.

During the three-month and six-month periods ended June 30, 2017, there were no material changes to our critical accounting policies. Our critical accounting policies are described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2016.

## Results of Operations

### Comparison of the Three-Month Periods Ended June 30, 2017 and 2016

	Three Months Ended June 30,		Change
	2017	2016	
Contract revenue	\$ 1,266	\$ 9,144	\$ (7,878)
Operating expenses			
Research and development	22,199	21,708	491
General and administrative	8,860	3,951	4,909
Total operating expenses	31,059	25,659	5,400
Loss from operations	(29,793)	(16,515)	(13,278)
Interest expense	(723)	(447)	(276)
Change in warrant and derivative liabilities	4,225	(1,382)	5,607
Other income, net	221	76	145
Net loss	\$ (26,070)	\$ (18,268)	\$ (7,802)

### Contract Revenue

Contract revenue in each period related solely to funding pursuant to our Revenue Contracts. Contract revenue decreased \$7.8 million to \$1.3 million in the three-month period ended June 30, 2017 from \$9.1 million in the comparable period in 2016. This decrease was primarily due to the full utilization of BARDA funding available under the current contract.

### Research and Development Expenses

Research and development expenses increased \$0.5 million to \$22.2 million in the three-month period ended June 30, 2017 from \$21.7 million in the comparable period in 2016. This was primarily due to increases of \$6.2 million in personnel and facility related costs as net headcount increased by 46 employees in our research and development organization since June 2016, including \$0.9 million for stock compensation expense, \$2.2 million in external expenses related to C-Scape, mainly attributed to costs for our Phase 1 study, offset by a decrease of \$1.2 million in external non-clinical costs for other research programs, and \$6.7 million in the external expenses related to our plazomicin program, mainly attributable to the completion of the Phase 3 studies.

We record research and development expenses by program where directly identifiable. In the table below, we have allocated indirect research and development costs based on time charged directly to programs by research and development employees. Indirect research and development costs include employee benefit expenses, employee time not charged directly to a program, laboratory supplies and expenses, and allocated facility expenses.

	<u>Three Months Ended June 30,</u>		<u>Change</u>
	<u>2017</u>	<u>2016</u>	
	(in thousands)		
Research and development expenses by program:			
Plazomicin	\$ 13,205	\$ 16,556	\$ (3,351)
C-Scape	4,346	—	\$ 4,346
Other research programs	4,648	5,152	(504)
Total research and development expenses	<u>\$ 22,199</u>	<u>\$ 21,708</u>	<u>\$ 491</u>

#### *General and Administrative Expenses*

General and administrative expenses increased \$4.9 million to \$8.9 million for the three-month period ended June 30, 2017 from \$4.0 million for the comparable period in 2016. The increase in general and administrative expenses was primarily due to an increase of \$4.0 million in personnel and facility related costs, including \$1.6 million for stock compensation expense, as net headcount increased by 22 employees, and an increase of \$0.9 million in costs to prepare for commercialization of plazomicin.

#### *Interest Expense*

Interest expense increased \$0.3 million to \$0.7 million for the three-month period ended June 30, 2017 from \$0.4 million for the comparable period in 2016. The increase was a result of an additional \$10.0 million of borrowings under the Solar Capital loan agreement in June 2016.

#### *Change in Warrant and Derivative Liabilities*

Change in warrant and derivative liabilities decreased by \$5.6 million to a \$4.2 million gain for the three-month period ended June 30, 2017 from a \$1.4 million expense for the comparable period in 2016. The decrease is primarily due to the change in the estimated fair value of the warrant liability, which decreased mainly due to the change in our stock price.

#### **Comparison of the Six-Month Periods Ended June 30, 2017 and 2016**

	<u>Six Months Ended June 30,</u>		<u>Change</u>
	<u>2017</u>	<u>2016</u>	
Contract revenue	\$ 8,729	\$ 14,993	\$ (6,264)
Operating expenses			
Research and development	40,797	35,601	5,196
General and administrative	15,609	7,728	7,881
Total operating expenses	<u>56,406</u>	<u>43,329</u>	<u>13,077</u>
Loss from operations	(47,677)	(28,336)	(19,341)
Interest expense	(1,430)	(885)	(545)
Change in warrant and derivative liabilities	(10,731)	(1,382)	(9,349)
Other income, net	510	138	372
Net loss	<u>\$ (59,328)</u>	<u>\$ (30,465)</u>	<u>\$ (28,863)</u>

#### *Contract Revenue*

Contract revenue in each period related solely to funding pursuant to our Revenue Contracts. Contract revenue decreased \$6.3 million to \$8.7 million in the six-month period ended June 30, 2017 from \$15.0 million in the comparable period in 2016. This decrease was primarily due to the full utilization of BARDA funding available under the current contract.

#### *Research and Development Expenses*

Research and development expenses increased \$5.2 million to \$40.8 million in the six-month period ended June 30, 2017 from \$35.6 million in the comparable period in 2016. This was primarily due to increases of \$11.7 million in personnel and facility related costs as net headcount increased by 46 employees in our research and development organization since June 2016, including \$2.0 million for stock compensation expense, of which \$0.6 million of expense relate to equity awards held by our former Chief Medical

Officer that were modified in connection with his resignation in March 2017, \$3.4 million in external expenses related to C-Scape, mainly attributed to costs for our Phase 1 study, offset by a decrease of \$1.3 million in external non-clinical costs for other research programs and a decrease of \$8.6 million in the external expenses related to our plazomicin program, mainly attributable to the completion of the Phase 3 studies.

We record research and development expenses by program where directly identifiable. In the table below, we have allocated indirect research and development costs based on time charged directly to programs by research and development employees. Indirect research and development costs include employee benefit expenses, employee time not charged directly to a program, laboratory supplies and expenses, and allocated facility expenses.

	Six Months Ended June 30,		
	2017	2016	Change
(in thousands)			
<b>Research and development expenses by program:</b>			
Plazomicin	\$ 25,449	\$ 27,819	\$ (2,370)
C-Scape	6,996	—	\$ 6,996
Other research programs	8,352	7,782	570
<b>Total research and development expenses</b>	<b>\$ 40,797</b>	<b>\$ 35,601</b>	<b>\$ 5,196</b>

#### *General and Administrative Expenses*

General and administrative expenses increased \$7.9 million to \$15.6 million for the six-month period ended June 30, 2017 from \$7.7 million for the comparable period in 2016. The increase in general and administrative expenses was primarily due to an increase of \$6.0 million in personnel and facility related costs, including \$2.3 million for stock compensation expense, as net headcount increased by 22 employees, an increase of \$1.8 million in costs to prepare for commercialization of plazomicin and \$0.1 million in consulting and professional fees.

#### *Interest Expense*

Interest expense increased \$0.5 million to \$1.4 million for the six-month period ended June 30, 2017 from \$0.9 million for the comparable period in 2016. The increase was a result of an additional \$10.0 million of borrowings under the Solar Capital loan agreement in June 2016.

#### *Change in Warrant and Derivative Liabilities*

Change in warrant and derivative liabilities increased to \$10.7 million for the six-month period ended June 30, 2017 from \$1.4 million for the comparable period in 2016. The increase is primarily due to the change in the estimated fair value of the warrant liability, which increased mainly due to the change in our stock price.

### **Liquidity and Capital Resources**

	Six Months Ended June 30,	
	2017	2016
(in thousands)		
<b>Cash Flows from Continuing Operations:</b>		
Net cash used in operating activities	\$ (33,398)	\$ (23,809)
Net cash provided by (used in) investing activities	(62,574)	22,578
Net cash provided by financing activities	133,196	35,593
<b>Net increase in cash, cash equivalents and restricted cash</b>	<b>\$ 37,224</b>	<b>\$ 34,362</b>

#### *Cash Flows from Operating Activities*

Net cash used in operating activities was \$33.4 million for the six-month period ended June 30, 2017. The primary use of cash was to fund our operations related to the research and development of our product candidates. Our net loss from operations in the six-month period ended June 30, 2017 of \$59.3 million was partially offset by non-cash charges of \$10.7 million for the revaluation of the warrant and derivative liabilities, \$6.4 million for stock-based compensation, \$0.4 million for depreciation and amortization, \$0.4 million for non-cash interest expense, \$0.1 million for loss on fixed asset disposition and a change in net operating assets and liabilities of \$7.9 million. The change in net operating assets and liabilities was primarily due to an increase in accounts payable, accrued liabilities and prepaid expenses and other assets, as a result of commitments and deferred research and development costs

related to our commercial validation and manufacturing for plazomicin, partially offset by an increase in deferred revenue, as a result of the Advance Funds received under the grant agreement with the Gates Foundation, and a decrease in contract receivables.

Net cash used in operating activities was \$23.8 million for the six-month period ended June 30, 2016. The primary use of cash was to fund our operations related to the research and development of our product candidates. Our net loss from operations in the six-month period ended June 30, 2016 of \$30.5 million was partially offset by non-cash charges of \$1.4 million for the revaluation of the warrant and derivative liabilities, \$0.2 million for depreciation and amortization, \$0.3 million for amortization of premium on short-term investments, \$0.3 million for non-cash interest expense, \$1.8 million for stock-based compensation, and a change in net operating assets and liabilities of \$2.8 million. The change in net operating assets and liabilities was primarily due to an increase in accounts payable and accrued liabilities partially offset by an increase in contract receivable and prepaid expenses and other assets, as a result of costs for our ongoing Phase 3 EPIC trial and the timing of our payments.

#### *Cash Flows from Investing Activities*

Net cash used in investing activities was \$62.6 million for the six-month period ended June 30, 2017. The net cash used in investing activities during the six-month period ended June 30, 2017 is primarily a result of purchases in excess of maturities of short-term investments of \$59.4 million and purchases of property, plant and equipment of \$3.2 million related to our move into new corporate headquarters and to facilitate our research and development activities.

Net cash provided by investing activities was \$22.6 million for the six-month period ended June 30, 2016. The net cash provided by investing activities during the six-month period ended June 30, 2016 is primarily a result of maturities in excess of purchases of short-term investments of \$22.9 million. Other uses of cash in both periods resulted from purchases of property, plant and equipment to facilitate our increased research and development activities.

#### *Cash Flows from Financing Activities*

Net cash provided by financing activities was \$133.2 million and \$35.6 million for the six-month period ended June 30, 2017 and 2016, respectively. The net cash provided by financing activities during the six-month period ended June 30, 2017 includes \$121.2 million of net proceeds, after deducting the underwriting discounts and commissions, from an underwritten public offering of our common stock in May 2017, approximately \$10.0 million of net proceeds, after deducting issuance costs, from the sale of contingently redeemable common stock to the Gates Foundation in May 2017, \$1.7 million from the issuance of common stock pursuant to our equity incentive plans and \$0.3 million of proceeds from the exercise of certain warrants issued from the Private Placement. The net cash provided by financing activities during the six-month period ended June 30, 2016 includes \$25.4 million for the sale of common stock and warrants to purchase common stock from the Private Placement, \$10.0 million from the term loan provided by Solar Capital Ltd. in June 2016, and \$0.2 million from issuance of common stock pursuant to our equity incentive plans.

#### *Plan of Operations and Future Funding Requirements*

We expect to incur substantial expenditures in the foreseeable future for research, development and potential commercialization of our product candidates. Specifically, we have incurred and we expect to continue to incur substantial expenses in connection with our clinical development of plazomicin and C-Scape and the advancement our research and development programs. Management expects that, based on its current operating plans, our existing cash, cash equivalents and short-term investments as of June 30, 2017 will be sufficient to fund our current planned operations for at least the next twelve months from the issuance of these financial statements.

We anticipate that we will need to raise substantial additional financing in the future to fund our operations. We may obtain additional financing through public or private equity offerings, debt financings, a credit facility, government contracts and/or strategic collaborations. Additional financing may not be available to us when we need it or it may not be available to us on acceptable terms, if at all. Our ability to obtain debt financing may be limited by covenants we have made under our loan and security agreement with Solar Capital Ltd. and our pledge to Solar Capital Ltd. of substantially all of our assets, other than our intellectual property, as collateral. The negative pledge in favor of Solar Capital Ltd. with respect to our intellectual property under the loan and security agreement could further limit our ability to obtain additional debt financing. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies.

The amount and timing of our future financing requirements will depend on many factors, including:

- the size, timing and type of the nonclinical and clinical studies that we decide to pursue in the development of our product candidates, including plazomicin;
- the type, number, costs and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;

- the rate of progress and cost of clinical trials we may commence, preclinical studies and other discovery and research and development activities;
- the costs associated with developing a plazomicin IVD assay to support therapeutic drug monitoring;
- the timing of, and costs involved in, seeking and obtaining FDA and other regulatory approvals, including the preparation of an NDA for plazomicin, and any supplemental applications thereto;
- our ability to enter into additional collaboration, licensing or other arrangements and the terms and timing of such arrangements;
- the costs of preparing, filing, prosecuting, maintaining and enforcing any patent claims and other intellectual property rights, including litigation costs and the results of such litigation;
- the emergence of competing technologies and other adverse market developments;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- our ability to enter into additional government contracts, or other collaborative agreements, to support the development of our product candidates and development efforts; and
- the costs associated with being a public company.

### **Contractual Obligations and Commitments**

There have been no material changes to our contractual obligations and commitments as included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the “SEC”) on March 14, 2017, except as noted below:

- In July 2017, we entered into a lease amendment (the “Lease Amendment”) to our existing lease (the “Lease”) to lease an additional 51,866 square feet of office, laboratory and research and development space located at our current principal executive offices. The amount of future minimum lease payments under the Lease and the Lease Amendment are \$31.9 million and \$39.3 million, respectively, for a total aggregate amount of \$71.2 million. See Note 10 and 11 of the accompanying unaudited condensed consolidated financial statements for more information on the Lease and Lease Amendment, respectively.
- In March 2017, we executed certain work plans with Hovione Limited (“Hovione”) to carry out our validation and commercial manufacturing of plazomicin (the “Work Plans”). The Work Plans include certain terms that require us to compensate Hovione if we choose to cancel the Work Plans (“Cancellation Clause”). The total aggregate amount of potential commitments under the Work Plans is approximately \$28.1 million, of which \$9.8 million is committed under the Cancellation Clause, as of June 30, 2017. See Note 10 of the accompanying unaudited condensed consolidated financial statements for more information.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

There have not been any material changes to our exposure to market risk during the three-month and six-month periods ended June 30, 2017. For additional information regarding market risk, refer to the *Quantitative and Qualitative Disclosures About Market Risk* section of our Annual Report on Form 10-K for the year ended December 31, 2016.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated



to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of such date. This conclusion was based on the material weakness in our internal control over financial reporting further described below.

### **Material Weakness**

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected and corrected on a timely basis. In connection with the preparation of our interim financial statements for the quarter ended June 30, 2017, we identified a material weakness in our internal control over financial reporting related to a design deficiency in our internal controls over the preparation and review of our earnings per share calculation. Specifically, our controls were not adequately designed to ensure that all potentially dilutive securities were accurately reflected in the calculation of our diluted earnings per share.

Despite the existence of this material weakness, we believe that the consolidated financial statements included in this Quarterly Report on Form 10-Q present fairly, in all material respects, our financial position, results of operations, comprehensive loss and cash flows for the periods presented in conformity with U.S. GAAP.

### **Remediation Efforts to Address Material Weakness**

We have prepared a preliminary remediation plan to address the underlying causes of the material weakness described above. The preliminary remediation plan includes;

- Reassessing the design and operation of internal controls over financial reporting, including setting up a model with sufficient detail to ensure that all potentially dilutive securities were accurately reflected in the calculation of our diluted earnings per share;
- Training of accounting personnel to further educate the staff on the accounting of new and ongoing complex and/or technical transactions relevant to us; and
- Increasing staffing levels and expertise to implement this remediation plan.

We cannot assure you that the measures we may take in response to this material weakness will be sufficient to remediate such material weakness or to avoid potential future material weaknesses.

### **Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q 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.

We are not currently a party to any material litigation or other material legal proceedings.

### Item 1A. Risk Factors.

#### Risks Related to Our Business and Capital Requirements

*We have a limited operating history, have incurred net losses in each year since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.*

We are a late-stage biopharmaceutical company with a limited operating history. We have not generated any revenue from the sale of products and have incurred losses in each year since we commenced operations in 2004. All of our product candidates are in development, and none has been approved for sale. In the years ended December 31, 2016 and 2015 and the six-month period ended June 30, 2017, we derived all of our revenue from non-profit foundation and government contracts for research and development. We will seek continued revenue from such contracts and additional sources of public health funding. Revenues from such contracts and other sources can be uncertain because milestones or other contingent payments under them may not be achieved or received. In addition, we may not be able to enter into other contracts that will generate significant cash. Our net losses for the years ended December 31, 2016 and 2015 were \$71.2 million and \$27.1 million, respectively. Our net losses for the six-month periods ended June 30, 2017 and 2016 were \$59.3 million and \$30.5 million, respectively. As of June 30, 2017, we had an accumulated deficit of \$306.5 million.

We expect to continue incurring significant expenses and increasing operating losses for the foreseeable future as we seek marketing approvals from the U.S. Food and Drug Administration (“FDA”) and similar regulatory authorities outside the United States, build commercial supply and conduct pre-marketing activities for plazomicin, and continue the development of our other product candidates. Our expenses will also increase substantially if and as we:

- conduct additional clinical trials for our product candidates;
- continue to discover and develop additional product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- establish a manufacturing and supply chain sufficient for commercial quantities of any product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as operating as a public reporting company; and
- acquire or in-license other product candidates and technologies.

If our product candidates fail to demonstrate safety and efficacy in clinical trials, do not gain regulatory approval, or do not achieve market acceptance following regulatory approval and commercialization, 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 prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity and working capital. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

***We are substantially dependent on the approval and success of our lead product candidate, plazomicin. If we are unable to obtain marketing approval for and successfully commercialize plazomicin, or experience significant delays in doing so, our business could be materially harmed.***

We currently have no products approved for sale, and since 2007, we have invested a significant portion of our efforts and financial resources in the development of plazomicin. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for and, ultimately, successfully commercialize plazomicin. Our ability to develop, obtain regulatory approval for, and successfully commercialize plazomicin effectively will depend on several factors, including the following:

- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- receiving the product labeling that enables the successful promotion of plazomicin;
- satisfying post-approval conditions or suggestions, if any, based on discussions with FDA;
- establishing commercial manufacturing and supply arrangements;
- establishing a commercial infrastructure;
- identifying and successfully establishing one or more collaborations to commercialize plazomicin;
- acceptance of the product by patients, the medical community and third-party payors;
- establishing market share while competing with other therapies;
- successfully executing our pricing and reimbursement strategy;
- a continued acceptable safety and adverse event profile of the product following regulatory approval; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering the product.

In addition, our product development and commercialization program includes the development of an *in vitro* diagnostic (“IVD”) assay or related diagnostic which must be developed and would need to successfully complete a clinical performance study in order to be approved or cleared for marketing by the FDA and certain other foreign regulatory agencies and then be commercialized concurrently with plazomicin in the associated markets for the appropriate populations. If we are unable to develop, receive marketing approval for plazomicin or an IVD assay in a timely manner or at all, we could experience significant delays to successfully commercialize plazomicin, which would materially and adversely affect our business, financial condition, and results of operations.

***We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts and this would impact our status as a going concern.***

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is an expensive and highly uncertain process that takes years to complete. We expect our expenses to increase substantially as we seek marketing approval for our lead product candidate, plazomicin, and continue the development of our other product candidates. If we obtain marketing approval of plazomicin, we also expect to incur significant sales, marketing, manufacturing and supply expenses.

As of June 30, 2017, we had working capital of \$218.6 million and unrestricted cash, cash equivalents and short-term investments of \$230.3 million. Management expects that, based on its current operating plans, our existing cash, cash equivalents and short-term investments as of June 30, 2017, will enable us to fund our current planned operations for at least the next twelve months. In addition, other factors may arise causing us to need additional capital resources sooner than anticipated. We anticipate that we will need to raise substantial additional funds in the future to fund our operations.

We may obtain additional financing through multiple sources, including but not limited to public or private equity offerings, debt financings, a credit facility, government contracts and/or strategic collaborations. Additional financing may not be available to us when we need it or it may not be available to us on acceptable terms, if at all. Our ability to obtain debt financing may be limited by covenants we have made under our loan and security agreement with Solar Capital Ltd. and our pledge to Solar Capital Ltd. of substantially all of our assets, other than our intellectual property, as collateral. The negative pledge in favor of Solar Capital Ltd. with respect to our intellectual property under the loan and security agreement could further limit our ability to obtain additional debt

financing. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. The amount and timing of our future financing requirements will depend on many factors, including:

- the size, timing and type of the nonclinical and clinical studies that we decide to pursue in the development of our product candidates, including plazomicin;
- the type, number, costs and results of the product candidate development programs that we are pursuing or may choose to pursue in the future;
- the rate of progress and cost of clinical trials we may commence, preclinical studies and other discovery and research and development activities;
- the costs associated with developing a plazomicin IVD assay or related diagnostic to support therapeutic drug monitoring;
- the timing of, and costs involved in, seeking and obtaining FDA and other regulatory approvals, including the preparation of an NDA for plazomicin, and any supplemental applications thereto;
- our ability to enter into additional collaboration, licensing or other arrangements and the terms and timing of such arrangements;
- the costs of preparing, filing, prosecuting, maintaining and enforcing any patent applications or claims and other intellectual property rights, including litigation costs and the results of such litigation;
- the emergence of competing technologies and other adverse market developments;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- our ability to enter into additional government contracts, or other collaborative agreements, to support the development of our product candidates and development efforts; and
- the costs associated with being a public company.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no understandings, commitments or agreements relating to any of these types of transactions.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials and we may not be able to continue as a going concern. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

***Clinical drug development involves a lengthy and expensive process with uncertain outcomes that may lead to delayed timelines and increased cost, and may prevent us from being able to complete clinical trials.***

Clinical testing is expensive, can take many years to complete, and its outcome and timeline is inherently uncertain. The results of preclinical and clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

We expect to submit a New Drug Application (“NDA”) for plazomicin in the second half of 2017, with a planned commercial launch of plazomicin in the U.S. in 2018, if our NDA is approved. We also plan to submit a Marketing Authorization Application to the European Medicines Agency (“EMA”) for plazomicin in 2018.

We plan to submit the results to a peer-reviewed journal in 2017. Based on physician market research, we believe the Phase 3 CARE study will provide important and meaningful data regarding the efficacy, safety, microbiology, and dosing, as well as important health economic data, to better inform use of plazomicin in the treatment of patients with CRE infections.

We cannot be certain that our future clinical trials for plazomicin, C-Scape, or other product candidates, will progress as expected, not need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all, or support continued clinical development of the associated product candidate.

Clinical trials can be delayed, aborted or fail for a variety of reasons, including delay or failure:

- to obtain regulatory approval to commence a trial in the countries where the trial is to be conducted;
- to successfully initiate a clinical trial, enroll patients, and complete clinical trial activities in foreign countries;
- to recruit and enroll suitable patients to participate in a trial;
- to reach agreement on acceptable terms with prospective contract research organizations (“CROs”), clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- to obtain institutional review board (“IRB”) approval at each site;
- to have patients complete a trial or return for post-treatment follow-up;
- of clinical sites to adhere to trial protocols or continue to participate in a trial;
- to address any patient safety concerns that arise during the course of a trial;
- to address any conflicts with new or existing laws or regulations;
- to add a sufficient number of clinical trial sites;
- to manufacture sufficient quantities of product supply for use in clinical trials; or
- to ensure clinical trial sites comply with Good Clinical Practice (“GCP”) guidelines.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product development and approval processes, and jeopardize our ability to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed. Patient enrollment in clinical trials is a function of many factors, including: the nature of clinical trial protocols, existence of competing protocols or treatments (if any), the size and longevity of the target patient population, proximity of patients to clinical sites and eligibility criteria for the clinical trials. Although we will continue to look for opportunities for faster regulatory approval of plazomicin or our other product candidates, we cannot guarantee that additional opportunities will arise, that the FDA or other regulatory authorities will agree with any additional proposals we make or that such additional proposals, even if approved, will be successful.

We could also encounter delays if a clinical trial is suspended or terminated by us upon recommendation of the data monitoring committee for such trial, by the IRBs of the institutions in which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenue from the sale of any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval processes, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects.

***The revisions to our Phase 3 CARE trial protocol did not allow it to be powered to demonstrate a superiority outcome and the FDA, the EMA and other regulatory authorities as well as physicians and other third parties may not consider the data from our Phase 3 CARE trial to be supportive of plazomicin’s potential to address serious bacterial infections caused by CRE.***

Cohort 1 of our Phase 3 CARE trial was originally planned and the size estimated based on a superiority design. We decided to reduce the planned enrollment of our Phase 3 CARE trial. However, with this reduced sample size, the study was not powered to demonstrate superiority. Our ability to claim certain of the market and label benefits that a successful superiority trial would have provided, are reduced because we completed Cohort 1 of the trial with a reduced enrollment size in our Phase 3 CARE trial. Further,

because of this, the FDA, the EMA and other regulatory authorities as well as physicians and other third parties may not consider the data from our Phase 3 CARE trial to be supportive of plazomicin's potential to address serious bacterial infections caused by CRE.

***Failure to successfully develop, validate and obtain regulatory clearance or approval of a plazomicin IVD assay or related diagnostic could harm our development and commercialization strategy for plazomicin for the treatment of serious bacterial infections caused by CRE.***

An important element of our development and commercialization strategy for plazomicin for the treatment of serious bacterial infections caused by CRE is the development of an IVD assay or related diagnostic to support the Therapeutic Drug Management ("TDM") of patients dosed with plazomicin; the plazomicin IVD assay is intended to measure levels of plazomicin in the blood so patients can receive safe and efficacious doses of plazomicin. In collaboration with ARK Diagnostics, Inc. ("ARK"), we previously co-developed such an assay for use in our Phase 3 CARE study and we are currently co-developing and intend to commercialize an assay capable of use with plazomicin, if approved.

We, and our partner, Microgenics Corporation (a part of Thermo Fisher Scientific, Inc.) ("Thermo Fisher") are co-developing a diagnostic assay for plazomicin and intend to work together to generate the data required for submission of either a 510(k) submission or a Premarket Approval (PMA) application to the FDA. The ability to collect such data and to prepare such a submission can be impacted by a variety of financial, clinical, and regulatory factors that could impact our timing and the ultimate availability of such an assay.

IVD assays can be subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and therefore require separate regulatory clearance or approval prior to commercialization. The development of a new IVD assay for a novel therapeutic such as plazomicin can be complex from an operational and regulatory perspective because of the need for both the drug and the diagnostic to receive regulatory clearance or approval. Should the regulatory clearance or approval process for our IVD assay be delayed, it could impact our ability to successfully commercialize plazomicin for the treatment of certain patients.

It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of a plazomicin assay during the development and regulatory approval process. We, or our other current or future collaboration partners may encounter difficulties in developing, obtaining regulatory clearance or approval for, and manufacturing of, an assay with appropriate quality standards, similar to those we face with respect to our drug product candidates themselves. Failure to overcome these hurdles could have an adverse effect on our ability to obtain regulatory clearance or approval for or to obtain market acceptance for and to commercialize an IVD assay or plazomicin.

***If the FDA does not conclude that our product candidate, C-Scape, satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval under Section 505(b)(2) are not as we expect, the approval pathway for C-Scape will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.***

We intend to pursue clinical trials and, if successful, seek FDA approval through the 505(b)(2) regulatory pathway for our product candidate, C-Scape, which is a combination of two previously-approved drugs. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for C-Scape as anticipated, we may need to conduct additional clinical trials beyond our current expectations, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for C-Scape would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than C-Scape, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for C-Scape, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. In addition, it is possible competitors or others will file citizens' petitions with the FDA in an attempt to persuade the FDA that C-Scape, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors or others could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

***If we fail to demonstrate the safety and efficacy of plazomicin or any other product candidate that we develop to the satisfaction of the FDA or comparable foreign regulatory authorities we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of plazomicin or such other product candidate. This would adversely impact our ability to generate revenue, our business and our results of operations.***

We are not permitted to commercialize, market, promote, or sell any product candidate in the United States without obtaining marketing approval from the FDA or in other countries without obtaining approvals from comparable foreign regulatory authorities,

such as the EMA, and we may never receive such approvals. To gain approval to market a drug product, we must complete extensive preclinical development and clinical trials that demonstrate the safety and efficacy of the product for the intended indication to the satisfaction of the FDA or other regulatory authority.

We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that plazomicin will receive regulatory approval. Further, plazomicin may not receive regulatory approval even though it was successful in certain clinical trials. If we do not receive regulatory approval for plazomicin, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market plazomicin, our revenue from this approval will be dependent, in part, upon our or a commercial partner's ability to obtain regulatory approval of an IVD assay to be used with plazomicin for the treatment of serious bacterial infections caused by CRE, as well as upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights.

The FDA or any foreign regulatory agencies can delay, limit, or deny approval of plazomicin for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency that plazomicin is safe and effective for the requested indication;
- our inability to demonstrate that plazomicin fits an appropriate profile in interacting with other possible drugs or treatment regimens;
- the FDA's or the applicable foreign regulatory agency's disagreement with the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of plazomicin outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical or clinical studies;
- the FDA's or the applicable foreign regulatory agency's non-approval of the formulation, labeling or the specifications of plazomicin;
- the FDA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract;
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval; or
- failure to adequately demonstrate study conduct oversight, ensure data integrity, and that clinical study sites complied with the principles of Good Clinical Practice, such that we do not pass pre-approval inspections by the FDA or other foreign regulatory agencies.

Even if we complete clinical testing and receive approval of an NDA or foreign regulatory filing for plazomicin, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or the applicable foreign regulatory agency also may approve plazomicin for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve the labeling that we believe is necessary or desirable for the successful commercialization of plazomicin. For example, we anticipate the NDA for plazomicin will initially be based on our Phase 3 EPIC trial and that, if approved, we anticipate the U.S. label will indicate that plazomicin is for use in patients with infections that have limited or no alternative antibiotic treatment options. In addition, we believe that the label will include *in vitro* data against antibiotic resistant pathogens in the microbiology section of the drug label. However, the FDA may approve a label that omits this *in vitro* data or that limits plazomicin to a more limited indication or narrower patient population, which may harm our ability to successfully commercialize plazomicin, if approved. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of plazomicin and would materially adversely impact our business and prospects. Any other product candidate we advanced to the marketing approval stage would also be subject to the risks delineated above.

***Serious adverse events or other unexpected properties of plazomicin, C-Scape, or any other product candidate may be identified during development or after approval that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.***

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If plazomicin or any of our other product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon their development or limit

development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

To date, plazomicin has generally been well tolerated in clinical trials conducted in healthy subjects, subjects with renal impairment, and in patients with cUTI, and in patients with serious infections due to CRE and there have been no reports of serious adverse events related to plazomicin in our completed clinical trials. Toxicity in the kidneys and inner ear are the most significant identified risks for plazomicin, which are well-known risks for the aminoglycoside class of antibiotics. Hypotension is also a potential risk for plazomicin.

Undesirable side effects or other unexpected adverse events or properties of plazomicin or any of our other product candidates could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, plazomicin or our other product candidates. If such an event occurs after plazomicin or such other product candidates are approved, a number of potentially significant negative consequences may result, including:

- regulatory authorities may withdraw the approval of such product;
- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- regulatory authorities may require one or more post-market studies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- healthcare providers may choose to treat patients with other drugs; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

***We cannot predict to what extent bacteria may develop resistance to plazomicin, C-Scape, or how resistance could spread, which could affect the revenue potential for plazomicin.***

We are developing plazomicin to treat multi-drug resistant (“MDR”) infections. The bacteria responsible for these infections evolve quickly and readily transfer their resistance mechanisms within and between species. Furthermore, some resistance to plazomicin already exists and we cannot predict how the prevalence of bacterial resistance to plazomicin will change over time.

As with some other commercially available aminoglycosides, plazomicin is not active against organisms expressing a resistance mechanism known as ribosomal methyltransferase. Although occurrence of this resistance mechanism among CRE varies regionally and is currently rare in the United States, there have been isolated cases of infections by bacteria carrying ribosomal methyltransferase in the United States. We cannot predict whether ribosomal methyltransferase will become widespread in regions where we intend to market plazomicin if it is approved. The growth of MDR infections in community settings or in countries with poor public health infrastructures, or the potential use of plazomicin outside of controlled hospital settings, could contribute to the rise of plazomicin resistance. If resistance to plazomicin becomes prevalent, our ability to generate revenue from plazomicin could suffer.

***We may become dependent on our partner Thermo Fisher to commercialize an IVD assay.***

We have entered into a collaboration with Thermo Fisher for the development and commercialization of a plazomicin IVD assay, we may be dependent on Thermo Fisher with respect to such manufacturing and supply and with respect to commercialization in the United States and the EU. This reduces our control over these activities but would not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards with respect to plazomicin.

We or Thermo Fisher may encounter difficulties in developing an assay for commercial application in one or more countries, including issues in relation to automation, selectivity/specificity, analytical validation, reproducibility, or clinical validation of such assay. If Thermo Fisher does not perform its contractual duties or obligations, experiences work stoppages, does not meet expected deadlines, terminates its agreements with us or needs to be replaced, or if they otherwise do not meet our expectations for development, manufacture or commercialization of the assay, we may need to enter into new arrangements with one or more

alternative third parties for development, manufacture or commercialization of the assay or an alternative assay. We may not be able to do so on commercially reasonable terms, or within the terms of the commercialization agreement without amending such terms, or at all, which could adversely impact our business and results of operations related to plazomicin for the treatment of serious bacterial infections caused by CRE.

***If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.***

Although a substantial amount of our efforts is focused, and will continue to be focused, on the potential approval of our lead product candidate, plazomicin, a key element of our strategy is to discover, develop and commercialize a portfolio of therapeutics to treat MDR bacterial infections and potentially additional disease areas. We are seeking to do so through our internal research programs and are exploring, and intend to explore in the future, strategic partnerships for the development of new products. Other than plazomicin and C-Scape, all of our other potential product candidates remain in the discovery and preclinical stages.

Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- we may be unable to successfully modify candidate compounds to be active in gram-negative bacteria or defeat bacterial resistance mechanisms or identify viable product candidates in our screening campaigns;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third party patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors; and
- the development of bacterial resistance to potential product candidates may render them ineffective against target infections.

We cannot guarantee that these efforts will be successful. If we identify viable product candidates, we would have to submit a new IND application for any compound we seek to advance to clinical trials.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired.

***Even if a product candidate does obtain regulatory approval it may never achieve market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success and the market opportunity may be smaller than we estimate.***

Even if we obtain FDA or other regulatory approvals, and are able to launch plazomicin or any other product candidate commercially, the product candidate may not achieve market acceptance among physicians, patients, hospitals (including pharmacy directors) and third-party payors and, ultimately, may not be commercially successful. Market acceptance and market opportunity of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety of the product candidate as demonstrated in clinical trials;
- relative convenience and ease of administration;
- the clinical indications for which the product candidate is approved;
- the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments;
- the willingness of physicians to prescribe the product;

- the willingness of hospital pharmacy directors to purchase our products for their formularies;
- acceptance by physicians, operators of hospitals and treatment facilities and parties responsible for reimbursement of the product;
- the availability of adequate coverage and reimbursement by third-party payors and government authorities;
- the effectiveness of our sales and marketing efforts;
- the strength of our marketing and distribution support;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved risk evaluation and mitigation strategy;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the approval of other new products for the same indications;
- the timing of market introduction of the approved product as well as competitive products;
- adverse publicity about the product or favorable publicity about competitive products;
- the emergence of bacterial resistance to the product candidate; and
- the rate at which resistance to other drugs in the target infections grow.

Any failure by plazomicin or any other product candidate that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

***The availability of adequate third-party coverage and reimbursement for approved products is uncertain, and failure to obtain adequate coverage and reimbursement from government and other third-party payors could impede our ability to market any future products we may develop and could limit our ability to generate revenue.***

There is significant uncertainty related to the third-party payor coverage and reimbursement of newly approved medical products. In addition, there is uncertainty for continued levels of reimbursement for any medical products in consideration of competition, issues concerning the global healthcare infrastructure and other issues that may be beyond our control. The commercial success of our future products in both domestic and international markets depends on whether third-party coverage and reimbursement is available and ongoing for our future products. Governmental payors, including Medicare and Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to manage their healthcare expenditures by limiting both coverage and the level of reimbursement of new drugs and biologics and, as a result, they may not cover or provide adequate reimbursement for our future products or related diagnostics. These payors may not view our future products as cost-effective, and coverage and reimbursement may not be available to our customers or may not be sufficient to allow our future products to be marketed on a competitive basis.

Third-party payors are exerting increasing influence on decisions regarding the use of, and coverage and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are challenging the prices charged for medical products and services, and many third-party payors limit or delay coverage and reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated revenue from the sale of our product candidates. If we decrease the prices for our product candidates or are unable to occasionally increase prices because of competitive pressures or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

In addition, to the extent that our product candidates will be used in a hospital inpatient setting, hospitals often receive fixed reimbursement for all of a patient's care, including the cost of our drug products and IVD assay, based on the patient's diagnosis. For example, Medicare reimbursement for hospital inpatient stays is generally made under a prospective payment system that is determined by a classification system known as the Medicare severity diagnosis-related groups. Our patients' access to adequate coverage and reimbursement by government and private insurance plans is central to the acceptance of our future products. We may be unable to sell our products on a profitable basis if third-party payors reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

We are developing our lead product candidate plazomicin for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including CRE, which constitute a growing but relatively small patient population. Antibiotics have historically been marketed towards broad patient populations at relatively low prices. Based on the high unmet medical need in the treatment of these infections and the high costs of treating antibiotic resistant infections, we are targeting value-based pricing for plazomicin. If hospitals or governmental or other third-party payors do not view the benefits of plazomicin as worth the cost, we will be unable to achieve our pricing and reimbursement objectives and our prospects for revenue and profitability will suffer.

***We rely on third parties to conduct some of our preclinical studies and all of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates.***

We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct our preclinical studies and clinical trials on our product candidates in compliance with applicable regulatory requirements. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our preclinical studies and clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and the applicable legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as current good clinical practices (“cGCPs”), for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. If we or any of our third party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, we are required to report certain financial interests of our third party investigators if these relationships exceed certain financial thresholds and meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by principal investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. Our clinical trials must also generally be conducted with products produced under current good manufacturing practice (“cGMP”) regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Many of the third parties with whom we contract may also have relationships with other commercial entities, some of which may compete with us. If the third parties conducting our preclinical studies or our clinical trials do not perform their contractual duties or obligations or comply with regulatory requirements we may need to enter into new arrangements with alternative third parties. This could be costly, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, or to commercialize such product candidate being tested in such studies or trials. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third party contractors or to do so on commercially reasonable terms. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***We rely on third-party contract manufacturing organizations to manufacture and supply plazomicin, C-Scape, and other product candidates for us, as well as certain raw materials used in the production thereof. If one of our suppliers or manufacturers fails to perform adequately we may be required to incur significant delays and costs to find new suppliers or manufacturers.***

We currently have limited experience in, and we do not own facilities for, manufacturing our product candidates, including plazomicin. We rely upon third-party manufacturing organizations to manufacture and supply our product candidates and certain raw materials used in the production thereof. Some of our key components for the production of plazomicin have a limited number of suppliers. In particular, sisomicin, the aminoglycoside precursor for plazomicin, is supplied by a single manufacturer in China for which we do not have a commercial supply agreement.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacture of our drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If any of the manufacturers receive warning letters or other notices of violations from the FDA or others, they may be unable to timely address the issues raised in such warnings or notices. This could cause a delay or inability to supply materials or services on a timely basis. There could also be a delay if we are required to seek additional or backup sources for any aspects of the manufacturing process. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality

control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it delays or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our third party suppliers may not be able to meet our supply needs or timelines and this may negatively affect our business. A majority of the manufacturing process is operated internationally, and therefore may be subject to similar risks of the sort described by the risk factor entitled “ *A variety of risks associated with international operations could materially adversely affect our business.* ”

The failure of third-party manufacturers or suppliers to perform adequately or the termination of our arrangements with any of them may adversely affect our business.

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

Certain existing suppliers we use are located outside of the United States, including our sole source supplier for sisomicin, a key raw material for the production of plazomicin, which is located in China, and for which we do not have a commercial supply agreement. Additionally, if plazomicin is approved for commercialization outside the United States, we will likely seek to enter into agreements with third parties to market plazomicin outside the United States. We are, or we expect that we will be, subject to additional risks related to these international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in certain foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- potential liability resulting from development work conducted by these third parties; and
- business interruptions resulting from geopolitical events, including war and terrorism, or natural disasters.

***We may be subject to costly product liability claims related to our clinical trials and product candidates and, if we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of our insurance coverage, a material liability claim could adversely affect our financial condition.***

Because we conduct clinical trials with human patients, we face the risk that the use of our product candidates may result in adverse side effects to patients in our clinical trials. We face even greater risks upon any commercialization of our product candidates. Although we have product liability insurance, which covers our clinical trials for up to \$5 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer, and we will be required to increase our product liability insurance coverage for our advanced clinical trials that we plan to initiate. We do not know whether we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, on acceptable terms, if at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates or products causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;

- regulatory investigations that could require costly recalls or product modifications;
- loss of revenue;
- substantial costs of litigation;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management’s attention from our business; and
- damage to our reputation and the reputation of our products.

Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

***If we fail to establish an effective distribution process, which includes utilizing cold-chain logistics for plazomicin and the associated IVD assay, our business may be adversely affected.***

We do not currently have the infrastructure necessary for distributing pharmaceutical products to patients. We intend to contract with a third-party logistics company to warehouse these products and distribute them, and we will require plazomicin and the associated IVD assay to be maintained at a controlled temperature for some of the distribution chain. Failure to secure contracts with a logistics company could negatively impact the distribution of plazomicin or the IVD assay. If we are unable to effectively establish and manage the distribution process, the commercial launch and sales of plazomicin and the associated IVD assay will be delayed or severely compromised and our results of operations may be harmed.

In addition, the use of third party distributors, including with respect to cold-chain logistics for plazomicin and the associated IVD assay, involves certain risks, including, but not limited to, risks that distributors or pharmacies will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using plazomicin or the IVD assay, or complaints regarding them;
- not effectively sell or support plazomicin or the associated IVD assay with sufficient cold storage;
- reduce their efforts or discontinue to sell or support plazomicin or the IVD assay;
- not devote the resources necessary to sell plazomicin or the IVD assay in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

Plazomicin is still undergoing evaluation for, and we expect our IVD assay will have, a room temperature shelf life. Currently cold-chain logistics is required and if we do not effectively maintain our cold-chain supply logistics, then we may experience an unusual number of product returns or out of date product. Any such failure may result in decreased product sales and lower product revenue, which would harm our business.

***We currently have limited sales and marketing and distribution staff. If we are unable to develop an adequate sales and marketing and distribution capability on our own or through third parties, we will not be successful in commercializing our future products.***

We currently have limited sales, marketing and distribution staff and no history in this capacity. To achieve commercial success for any approved product candidate, we must either develop an adequate sales, marketing and distribution organization or outsource these functions to third parties. If we rely on third parties for selling, marketing and distributing our approved products, any revenue we receive will depend upon the efforts of third parties, which may not be successful and are only partially within our control, and our product revenue may be lower than if we directly sold or marketed our products. If we are unable to enter into arrangements with third parties to sell, market and distribute product candidates for which we have received regulatory approval on acceptable terms or at all, we will need to market these products ourselves. This is likely to be expensive and logistically difficult, as it would require us to build our own sales, marketing and distribution capacity. We have no historical operations in this area, and if such efforts were necessary, we may not be able to successfully commercialize our future products. If we are not successful in commercializing our future

products, either on our own or through third parties, any future product revenue will be materially and adversely affected, which would harm our business.

***We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.***

The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to plazomicin and other product candidates that we may seek to develop or commercialize in the future. There are a number of pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of MDR infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, safer or less costly than plazomicin or any other product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

There are a variety of available therapies marketed for the treatment of MDR infections that we would expect would compete with plazomicin, including Avycaz™ (ceftazadime/avibactam), which is marketed by Allergan plc in the United States and marketed by Pfizer outside the United States, tigecycline, which is marketed by Pfizer as Tygacil®, other aminoglycosides that are generically available (such as gentamicin, amikacin, tobramycin), and polymyxins that are generically available (colistin and polymixin B). Many of the available therapies are well-established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. If plazomicin is approved, it may be priced at a premium over other competitive products. This may limit plazomicin's adoption for MDR gram-negative infections.

There are also a number of products in late-stage clinical development by third parties to treat MDR gram-negative infections. Tetrphase Pharmaceuticals, Inc. is developing eravacycline for complicated urinary and intra-abdominal infections. The Medicines Company is developing Meropenem-vaborbactam for cUTI and various infection types due to CRE. Merck & Co., Inc. is developing imipenem/relebactam for certain life-threatening infections caused by MDR strains, including infections due to metallo-β-lactamase producing gram-negative pathogens. Zavante Therapeutics, Inc. is developing ZTI-01 for cUTI. Shionogi is developing cefiderocol for carbapenem-resistant gram-negative pathogens. We may also eventually face competition from products in earlier development stage. If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than us, it could result in our competitors establishing a strong market position before we are able to enter the market.

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the Generating Antibiotics Incentives Now (“GAIN”) Act. The GAIN Act provides incentives for the development of new, qualified infectious disease products, including adding five years to the otherwise applicable regulatory exclusivity period. We requested and the FDA granted qualified infectious disease product designation for plazomicin for the treatment of hospital acquired bacterial pneumonia, ventilator-associated pneumonia, complicated intra-abdominal infections, cUTIs, and catheter-related bloodstream infections on December 14, 2014. The incentives provided under the GAIN Act, along with government contract funding and other incentives for antibiotic research, may result in more competition in the market for new antibiotics.

In addition to the GAIN Act, the 21st Century Cures Act was signed into law in December 2016. This act establishes a new approval process (Limited Population Antibacterial Drug or “LPAD”) for antimicrobials intended for the treatment of serious infections in limited patient populations with an unmet medical need. It also provides a mechanism to establish, update, and communicate susceptibility test interpretive criteria for antimicrobial drugs. Although the 21st Century Cures Act and other contemplated acts in this space can help or support Achaogen, they also increase competition in the market for antimicrobials and provide incentives for the potential of new competitors in this disease area.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

Finally, the success of any product that is successfully commercialized will depend in large part on our ability to prevent competitors from launching a generic version that would compete with such product. If such competitors are able to establish that our patents are invalid or not infringed by the generic version of our product, they may be able to launch a generic product prior to the expected expiration of our relevant patents, and any generic competition could have a material adverse effect on our business, results of operations, financial condition and prospects.

***We may attempt to form collaborations in the future with respect to our technology and product candidates, but we may not be able to do so, which may cause us to alter our development and commercialization plans.***

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. For example, we currently intend to identify one or more strategic partners for the commercialization of plazomicin, and we may also attempt to find one or more strategic partners for the development or commercialization of one or more of our other product candidates. We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure appropriate terms is time-consuming and complex. We may not be successful in our efforts to establish strategic partnerships for our product candidates and programs on terms that are acceptable to us, or at all.

Any delays in identifying suitable collaborators and entering into agreements to develop or commercialize our product candidates could negatively impact the development or commercialization of our product candidates in geographic regions where we do not have development and commercialization infrastructure. Absent a collaboration partner, we would need to undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidates or bring them to market and our business may be materially and adversely affected.

***We may be unable to realize the potential benefits of any collaboration.***

Even if we are successful in entering into a collaboration with respect to the development or commercialization of one or more product candidates, there is no guarantee that the collaboration will be successful. Collaborations may pose a number of risks, including:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the collaboration;
- collaborators may not perform their obligations as expected;
- collaborators may cease to devote resources to the development or commercialization of our product candidates if the collaborators view our product candidates as competitive with their own products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time-consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in us achieving revenue to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

As a result, a collaboration may not result in the successful development or commercialization of our product candidates.

***Our operating activities may be restricted as a result of covenants related to the indebtedness under our loan agreement and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.***

On August 5, 2015, we entered into a loan and security agreement with Solar Capital Ltd., pursuant to which Solar Capital Ltd. agreed to make available to us term loans with an aggregate principal amount of up to \$25 million, \$15 million of which was provided to us on August 5, 2015 and \$10 million of which was provided to us on June 20, 2016. Until we have repaid such indebtedness, the loan and security agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or

other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, or to encumber our intellectual property. Our business may be adversely affected by these restrictions on our ability to operate our business.

Additionally, we may be required to repay the outstanding indebtedness under the loan facility if an event of default occurs under the loan and security agreement. Under the loan and security agreement, an event of default will occur if, among other things, we fail to make payments under the loan and security agreement; we breach any of our covenants under the loan and security agreement, subject to specified cure periods with respect to certain breaches; the Lender determines that a material adverse change has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit the holder of indebtedness to accelerate the maturity of such indebtedness or that could have a material adverse change on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Solar Capital Ltd. could also exercise its rights as collateral agent to take possession of and to dispose of the collateral securing the term loans, which collateral includes substantially all of our property (excluding intellectual property, which is subject to a negative pledge). Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

***We may need to grow our organization, and we may experience difficulties in managing growth.***

As of June 30, 2017, we had 147 employees. We will need to expand our managerial, operational, financial and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize plazomicin or other product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our business strategy requires that we:

- manage all our planned clinical trials;
- manage our internal discovery and development efforts effectively while carrying out our contractual obligations to licensors, contractors, government agencies, any future collaborators and other third parties;
- conduct pre-commercial activities for plazomicin;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- identify, recruit, maintain, motivate and integrate additional employees.

If we are unable to expand our managerial, operational, financial and other resources to the extent required to manage our development and commercialization activities, our business will be materially adversely affected.

***We are highly dependent on the services of our executive team and our ability to attract and retain qualified personnel.***

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area. We are highly dependent on the principal members of our management and scientific staff, particularly our executive team. If we are not able to retain our executive team or are not able to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. Although we have executed employment agreements with each member of our current executive management team, we may not be able to retain their services as expected. In addition to the competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. Although we historically have not had any material difficulty attracting qualified experienced personnel to our company, we could in the future have such difficulties and may be required to expend significant financial resources in our employee recruitment and retention efforts.

In addition, we have scientific and clinical advisors who assist us in formulating our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

***Recent changes in our executive leadership and any similar changes in the future may serve as a significant distraction for our management and employees.***

Since the beginning of 2016, there have been a number of changes to our executive leadership team. In February 2017, we hired our Chief Commercial Officer, Janet Dorling, in November 2016, we hired our General Counsel, Gary Loeb, and in July 2016, we hired our Chief Financial Officer, Tobin Schilke. In March 2017, our former Chief Medical Officer, Ian Friedland, resigned and transitioned to a consulting position. Such changes, or any other future changes in our executive leadership, may disrupt our operations as we adjust to the reallocation of responsibilities and assimilate new leadership and, potentially, differing perspectives on our strategic direction. If the transition in executive leadership is not smooth, the resulting disruption could negatively affect our operations and impede our ability to execute our strategic plan.

***Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.***

Our third-party manufacturers' activities and our own activities involve the controlled storage, use and disposal of hazardous materials, including the components of our pharmaceutical product candidates, test samples and reagents, biological materials and other hazardous compounds. We and our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and/or interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations.

***Risks associated with a company-wide implementation of an enterprise resource planning, or ERP, system may adversely affect our business and results of operations or the effectiveness of our control environment.***

We are implementing a company-wide ERP system to handle the business and financial processes within our operations and corporate functions. ERP implementations are complex and time-consuming projects that involve substantial expenditures on system software and implementation activities. ERP implementations also require transformation of business and financial processes in order to reap the benefits of the ERP system. Our business and results of operations may be adversely affected if we experience operating problems or cost overruns during the ERP implementation process, or if the ERP system and the associated process changes do not give rise to the benefits that we expect. If we do not effectively implement the ERP system as planned or if the system does not operate as intended, it may adversely affect our ability to manage and run our business operations, file reports with the SEC in a timely manner, and/or otherwise affect our controls environment. Any of these consequences could have an adverse effect on our results of operations and financial condition.

***Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our business operations.***

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage or disruption from computer viruses, software bugs, unauthorized access, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures. While we have not, to our knowledge, experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential or proprietary information, we could incur liability, or adversely affect our business operations and/or financial condition.

***Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent

fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Prior to our initial public offering (“IPO”) in March 2014, we had not been subject to the reporting requirements of the Exchange Act of 1934, as amended (the “Exchange Act”), or the other rules and regulations of the Securities and Exchange Commission (the “SEC”) or any securities exchange relating to public companies. We continue to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public company. These areas include corporate governance, corporate control, disclosure controls and procedures and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. However, the expenses associated with being a public company could be material, particularly after we cease to be an “emerging growth company.” Based on our non-affiliated market capitalization as of June 30, 2017, we will cease to be an emerging growth company on January 1, 2018. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. In addition, the changes we make may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis.

In addition, certain types of insurance, including directors’ and officers’ liability insurance are more expensive as a public company. Being a public company could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

***If we are not able to implement the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 in a timely manner or with adequate compliance, we may be subject to sanctions by regulatory authorities.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on the internal control over financial reporting. If we have a material weakness in our internal controls over financial reporting, as occurred for the quarter ended June 30, 2017, we may not detect errors on a timely basis and our financial statements may be materially misstated. We will be evaluating our internal controls systems to allow management to report on, and eventually our independent auditors will attest to, the effectiveness of the operation of our internal controls. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and eventual auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. The aforementioned auditor attestation requirements will not apply to us until we are no longer considered an “emerging growth company.” Based on our non-affiliated market capitalization as of June 30, 2017, we will cease to be an emerging growth company on January 1, 2018.

We cannot be certain as to the timing of completion of our evaluation, testing and remediation action or the impact of the same on our operations. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, as occurred for the quarter ended June 30, 2017, we could be subject to sanctions or investigations by The NASDAQ Stock Market LLC, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources and could materially adversely affect our stock price. Deficient internal controls could also cause us to fail to meet our reporting obligations or cause investors to lose confidence in our reported financial information, which could have a negative effect on our stock price.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the acts of some individuals, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

For example, in connection with the preparation of our interim financial statements for the quarter ended June 30, 2017, we identified a material weakness in our internal control over financial reporting related to a design deficiency in our internal controls over the preparation and review of our earnings per share calculation. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected and corrected on a timely basis. Specifically, our controls were not adequately designed to ensure that all potentially dilutive securities were accurately reflected in the calculation of our diluted earnings per share.

We have prepared a preliminary remediation plan to address the underlying causes of the material weakness described above. The preliminary remediation plan includes;

- Reassessing the design and operation of internal controls over financial reporting, including setting up a model with sufficient detail to ensure that all potentially dilutive securities were accurately reflected in the calculation of our diluted earnings per share;
- Training of accounting personnel to further educate the staff on the accounting of new and ongoing complex and/or technical transactions relevant to us; and
- Increasing staffing levels and expertise to implement this remediation plan.

We cannot assure you that the measures we may take in response to this material weakness will be sufficient to remediate such material weakness or to avoid potential future material weaknesses.

Additionally, we cannot provide assurance that a similar material weakness will not recur, or that we will be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC when required. If we cannot in the future favorably assess, or our independent registered public accounting firm, when required, is unable to provide an unqualified attestation report on, the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price. In addition, any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The NASDAQ Global Market or other adverse consequences that would materially harm our business.

***We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our corporate headquarters is located in the San Francisco Bay Area, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our information technology systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are geographically concentrated and operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity by certain significant stockholders over a rolling three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future and/or subsequent shifts in

our stock ownership, some of which would be outside our control. If our ability to use our net operating losses and other tax attributes is limited by ownership changes, we may be unable to utilize a material portion of our net operating losses and other tax attributes.

### **Risks Related to Our U.S. Government Contracts and to Certain Grant Agreements**

***Our use of government funding for certain of our programs adds uncertainty to our research and commercialization efforts with respect to those programs and may impose requirements that increase the costs of commercialization and production of product candidates developed under those government-funded programs.***

Our development of plazomicin as a countermeasure for diseases caused by antibiotic-resistant pathogens and biothreats is currently being funded in significant part through a contract with BARDA. We are also receiving funding from the National Institute of Allergy and Infectious Diseases (“NIAID”) for one of our pre-clinical programs and we in the past received funding for other programs from the Defense Threat Reduction Agency (“DTRA”) and from NIAID. Contracts funded by the U.S. government and its agencies, including our contract with BARDA, include provisions that reflect the government’s substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government’s obligations under such agreements without the consent of the other party;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor from doing future business with the government;
- control and potentially prohibit the export of products; and
- pursue criminal or civil remedies under the False Claims Act (“FCA”), the False Statements Act and similar remedy provisions specific to government agreements.

We may not have the right to prohibit the U.S. government from using or allowing others to use certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally obtains the right to royalty-free use of technologies that are developed under U.S. government contracts.

In addition, government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, anti-human-trafficking, non-discrimination, and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with these requirements, we may be subject to potential contract or FCA liability and to termination of our contracts.

***U.S. go vernment agencies have special contracting requirements that give them the ability to unilaterally control our contracts.***

U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. These risks include the ability of the U.S. government to unilaterally:

- audit and object to our BARDA contract-related costs and fees, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or extending our existing contracts based on violations or suspected violations of laws or regulations;
- cancel, terminate or suspend our contracts based on violations or suspected violations of laws or regulations;
- terminate our contracts if in the government’s interest, including if funds become unavailable to the applicable governmental agency;
- reduce the scope and value of our contract; and
- change certain terms and conditions in our contract.

The U.S. government will be able to terminate any of its contracts with us, either for convenience or if we default by failing to perform in accordance with or to achieve the milestones set forth in the contract schedules and terms. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination-for-default provisions do not permit these recoveries and would make us liable for excess costs incurred by the U.S. government in procuring undelivered items from another source.

***The U.S. government’s determination to award a future contract or contract option may be challenged by an interested party, such as another bidder, at the U.S. Government Accountability Office (the “GAO”), or in federal court. If such a challenge is successful, our BARDA contract or any future contract we may be awarded may be terminated.***

The laws and regulations governing the procurement of goods and services by the U.S. government provide procedures by which other bidders and interested parties may challenge the award of a government contract. If we are awarded a government contract, such challenges or protests could be filed even if there are not any valid legal grounds on which to base the protest. If any such protests are filed, the government agency may decide to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to terminate any one or more of our contracts and reselect bids. The government agencies with which we have contracts could even be directed to award a potential contract to one of the other bidders.

***Our business is subject to audit by the U.S. government and other potential sources for grant funding, including under our contracts with BARDA, NIAID and the Gates Foundation, and a negative outcome in an audit could adversely affect our business.***

U.S. government agencies such as the Department of Health and Human Services (“DHHS”) and the Defense Contract Audit Agency (the “DCAA”) routinely audit and investigate government contractors. These agencies review a contractor’s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DHHS and the DCAA also review the adequacy of, and a contractor’s compliance with, its internal control systems and policies, including the contractor’s purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be paid, while such costs already paid must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease. We have also agreed to allow the Bill & Melinda Gates Foundation (the “Gates Foundation”) to audit our compliance with using specified proceeds from the Gates Foundation only for certain mutually-agreed upon work.

***Laws and regulations affecting government contracts make it more expensive and difficult for us to successfully conduct our business.***

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under our BARDA contract. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulations (“FAR”) and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and include other requirements such as the Anti-Kickback Statute and Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Any changes in applicable laws and regulations could restrict our ability to maintain our existing BARDA contract and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our results of operations.

**Risks Related to Intellectual Property**

***If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. However, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

Further, the patentability of inventions, and the validity, enforceability and scope of patents in the biotechnology and pharmaceutical field involve complex legal and scientific questions and can be uncertain. As a result, patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries for many reasons. For example, there is no assurance that we were the first to invent or the first to file patent applications in respect of the inventions claimed in our patent applications. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. We may also be unaware of certain prior art relating to our patent applications and patents, which could prevent a patent from issuing from a pending patent application, or result in an issued patent being invalidated. Even if patents have issued, or do successfully issue, from patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market any of our product candidates under patent protection, if approved, would be reduced. Changes to the patent laws in the United States and other jurisdictions could also diminish the value of our patents and patent applications or narrow the scope of our patent protection.

Further, one of our proposed development candidates, C-Scape, involves an innovative treatment combination of two previously-identified and approved products. In addition to all of the risks and uncertainties with pharmaceutical candidates in general, these prior products have extensive patent and intellectual property portfolios that once protected them and may continue to protect

certain aspects of these products. Such portfolios create additional risks and uncertainties for our own ability to obtain material patent or intellectual property protection on our combination development candidate, including the possibility that existing patents or applications relate to and cover combinations of these same products or product classes and the possibility that prior patent positions on these compounds will make it more difficult for us to obtain our own affirmative patents in this area. Antibacterial products are commonly used in combination with one another in research, development and treatment. We may not be aware of all the ways these prior products have been used in combination and of the various intellectual property that may relate to such combination or combinations or the prior uses of these compounds that may prevent us from obtaining our own intellectual property.

***If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.***

In addition to the protection afforded by patents, we rely on confidential proprietary information, including trade secrets, and know-how to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Further, the laws of some foreign countries, including China, where we currently source raw materials for plazomicin, do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

***If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including proceedings such as post-grant review and inter partes review before the U.S. Patent and Trademark Office (“USPTO”). Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party’s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys’ fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may

require us to pay royalties and other fees that could be significant. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our patents, the patents of our licensors, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, in whole or in part, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent.

Interference or derivation proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and/or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions, including China, where we currently source raw materials for plazomicin. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates from third parties, we could lose license rights that are important to our business.***

While the primary patent family covering plazomicin is Achaogen-owned, our development and commercialization of plazomicin is subject to our license agreement with Ionis Pharmaceuticals, Inc. (formerly known as Isis Pharmaceuticals, Inc.), and a portion of the patent portfolio for our LpxC inhibitor program is in-licensed from UW. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations for achievement of certain milestones and royalties on product sales, as well as other material obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing collaborators may have the right to terminate the applicable license in whole or in part. The loss of our license agreement with Ionis Pharmaceuticals, Inc. could materially adversely affect our ability to proceed with the development or potential commercialization of plazomicin as currently planned, while the loss of our license agreement with UW could materially adversely affect our ability to proceed with any development or potential commercialization of our LpxC inhibitor program.

The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases, we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to consult and input into the patent prosecution and maintenance process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by an issued patent or pending patent application that we own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are

situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

***We do not have exclusive rights to intellectual property we developed under U.S. federally-funded research grants and contracts in connection with certain neglected diseases initiatives, including our collaboration with the Gates Foundation, and, in the case of those funded research activities, we could ultimately share or lose the rights we do have under certain circumstances. Provisions in our U.S. government contracts, including our contract with BARDA, may affect our intellectual property rights.***

Certain of our activities have been funded, and may in the future be funded, by the U.S. government, including our contract with BARDA. When new technologies are developed with U.S. government funding, the government obtains certain rights in any resulting patents, including the right to a nonexclusive license authorizing the government to use the invention under these rights may permit the government to disclose our confidential information to third parties and to exercise “march-in” rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States.

Under our Gates Foundation collaboration, our research with respect to certain antibody platform and treatment development in identified developing countries are subject to certain intellectual property rights held by the Gates Foundation. While we have rights to develop and commercialize these technologies, we are required to implement a global access program for such technologies and we may not be able to further develop or exploit in certain territories, primarily those considered as developing countries.

***Recent patent reform legislation and potential new legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

On September 16, 2011, the Leahy-Smith America Invents Act (the “AIA”) was signed into law. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The passage of the AIA in 2011 added a new procedure to U.S. patent law. This procedure, inter partes review (“IPR”), allows any member of the public to file a petition with the USPTO seeking the review of any issued U.S. patent. IPRs are conducted before Administrative Patent Judges in the USPTO using a lower standard of proof than used in Federal District Court. In addition, the challenged patents are not accorded the presumption of validity as they are in Federal District Court. There are now instances where generic drug companies and some investment funds are attempting to invalidate patents by filing IPR challenges in the USPTO. The USPTO has promulgated regulations and developed procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA, and in particular, the first to file provisions, did not come into effect until March 16, 2013. Accordingly, it is not yet clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Patent reform continues to be a topic that could arise in a number of legislative and regulatory proposals, in particular related to patents and their impacts on ability to compete in healthcare. We cannot predict the way such future legislation, regulations or administrative procedures could impact our patent rights.

***We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets of former or other employers.***

Many of our employees and consultants, including our senior management, have been employed or retained by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee’s or consultant’s former or other employer. We are not aware of any material threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one or more of our U.S. patents, if any, covering our approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

#### **Risks Related to Government Regulation**

***The regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining, or cause delays in obtaining, approvals for the commercialization of some or all of our product candidates, which will materially impair our ability to generate revenue.***

The design, development, research, testing, manufacturing, labeling, storage, recordkeeping, approval, selling, import, export, advertising, promotion, and distribution of drug products are subject to extensive and evolving regulation by federal, state and local governmental authorities in the United States, principally by the FDA, and foreign regulatory authorities, with regulations differing from country to country. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. Neither we nor any future collaboration partner is permitted to market plazomicin or any other product candidate in the United States until we receive regulatory approval of an NDA from the FDA.

We have not submitted an application or obtained marketing approval for plazomicin or any other product candidate anywhere in the world. An NDA must include extensive preclinical and clinical data and supporting information to establish to the FDA's satisfaction the product candidate's safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. Obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and any applicable collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Preclinical testing and clinical trials are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical trial could also cause the FDA or us to terminate a clinical trial or require that we repeat it or conduct additional clinical trials. Additionally, data obtained from preclinical studies and clinical trials can be interpreted in different ways and the FDA or other regulatory authorities may interpret the results of our studies and trials less favorably than we do. Even if we believe the preclinical or clinical data for a product candidate is promising, such data may not be sufficient to support approval by the FDA

and other regulatory authorities. Administering any product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials of such product candidates and result in the FDA or other regulatory authorities denying approval of such product candidates for any or all targeted indications. The FDA or other regulatory authorities may determine that plazomicin or any other product candidate that we develop is not effective, or is only moderately effective, or has undesirable or unintended side effects, toxicities, safety profile or other characteristics that preclude marketing approval or prevent or limit commercial use. In addition, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

The regulatory approval process is expensive and may take several years to complete. The FDA and foreign regulatory entities have substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

- product candidate may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may request additional analyses, reports, data and studies;
- the FDA may ask questions regarding, or adopt different interpretations of, data and results;
- the FDA might not approve our or our third-party manufacturer's processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

Although we have received FDA fast-track designation for our development of plazomicin to treat serious CRE infections, we cannot guarantee that we will experience a faster review or approval process compared to conventional FDA procedures. The FDA may withdraw fast-track designation if it believes that the designation is no longer supported by data from our clinical development program.

If any of our product candidates fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, or if we experience delays in obtaining regulatory approval, our business and results of operations will be materially and adversely harmed.

***Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.***

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies or surveillance to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion, recordkeeping and submission of safety and other post-market information. Manufacturers of our products and manufacturers' facilities are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and to comply with requirements concerning advertising and promotion for our products. If we, any future collaboration partner or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the collaboration partner, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA also imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off-label marketing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters or untitled letters;
- mandated modifications to promotional materials or the required provision of corrective information to healthcare practitioners;
- restrictions imposed on the product or its manufacturers or manufacturing processes;
- restrictions imposed on the labeling or marketing of the product;
- restrictions imposed on product distribution or use;
- requirements for post-marketing clinical trials;
- suspension of any ongoing clinical trials;
- suspension of or withdrawal of regulatory approval;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements;
- seizure or detention of our products;
- refusal to permit the import or export of our products;
- required entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- civil or criminal penalties; or
- injunctions.

Widely publicized events concerning the safety risk of certain drug products have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the imposition by the FDA of risk evaluation and mitigation strategies ("REMS") to ensure that the benefits of the drug outweigh its risks. In addition, because of the serious public health risks of high profile adverse safety events with certain products, the FDA may require, as a condition of approval, costly REMS programs.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or any future collaboration partner are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. For example, certain policies of the current administration may impact our business and industry. The current administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, a hiring freeze was ordered for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order,

the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, an Executive Order was issued, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our product candidates internationally.***

We may seek a distribution and marketing collaborator for plazomicin or other product candidates commercialized outside of the United States. In order to market our product candidates in the European Economic Area (the "EEA"), which is comprised of the 28 Member States of the EU, plus Norway, Iceland and Lichtenstein), and many other foreign jurisdictions, we or our collaboration partners must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA"). There are two types of marketing authorizations:

- the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as for drugs produced through certain specified biotechnological processes (such as recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, and hybridoma and monoclonal antibody methods), advanced therapy medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- national MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

We have had limited interactions with foreign regulatory authorities, and approval procedures vary among countries and can involve additional clinical testing. In addition, the time required to obtain approval from foreign regulatory authorities may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on our ability to obtain approval in other countries. The foreign regulatory approval process generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may or may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file, we may not receive necessary approvals to commercialize our product candidates in any market.

***Healthcare reform measures could hinder or prevent our product candidates' commercial success.***

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which is intended to contain or reduce the costs of medical products and services. For example, in March 2010, the President signed one of the most significant healthcare reform measures in decades, the Affordable Care Act ("ACA"). It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The ACA, among other things:

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- imposes a 2.3% medical device excise tax that manufacturers and importers will be required to pay on their sales of certain medical devices, which, under the Consolidated Appropriations Act, 2016, is suspended from January 1, 2016 to December 31, 2017, and, absent further legislative action, will be reinstated starting January 1, 2018;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- addresses new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extension products;
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- expands eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all or certain provisions of, the ACA. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the ACA and permits such legislation to pass with a majority vote in the Senate. There is still uncertainty with respect to the impact the current administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregated reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments, will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has also been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

***We are subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.***

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal

government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal physician sunshine requirements under the ACA, which require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the recently enacted ACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal and other related expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

#### **Risks Related to Our Common Stock**

***The price of our common stock may be volatile and our stockholders may not be able to resell shares of our common stock at or above the price they paid.***

There was no public market for our common stock prior to our IPO in March 2014, the trading volume of our common stock on The NASDAQ Global Market has been limited since then, and there can be no assurance that an active and liquid trading market for our common stock will be sustained. We cannot predict the extent to which investor interest in our company will lead to the development of or sustain an active trading market on The NASDAQ Global Market or otherwise or how liquid that market might become. If an active public market is not sustained, it may be difficult for stockholders to sell their shares of common stock at prices that are attractive to them, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products, product candidates or

technologies by using our shares of common stock as consideration. The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- announcements relating to our current development and commercialization program for product candidates, including but not limited to plazomicin;
- results from, or any delays in, clinical trial programs relating to our product candidates;
- delays in commercializing or obtaining regulatory approval for our product candidates;
- any need to suspend or discontinue clinical trials due to side effects or other safety risks, or any need to conduct studies on the long-term effects associated with the use of our product candidates;
- capital fundraising or other financing activities that contain onerous or unfavorable terms;
- manufacturing issues related to our product candidates for clinical trials or future products for commercialization;
- commercial success and market acceptance of our product candidates following regulatory approval;
- undesirable side effects caused by product candidates after they have entered the market;
- spread of bacterial resistance to our product candidates;
- ability to discover, develop and commercialize additional product candidates;
- announcements relating to collaborations that we may enter into with respect to the development or commercialization of our product candidates, or the timing of payments we may make or receive under these arrangements;
- announcements relating to the receipt, modification or termination of government contracts or grants, or the timing of payments we may receive under these arrangements;
- success of our competitors in discovering, developing or commercializing products;
- delay or failure to successfully develop, validate and obtain regulatory clearance or approval of plazomicin in vitro diagnostic assay;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims related to our clinical trials or product candidates;
- prevailing economic conditions;
- business disruptions caused by earthquakes or other natural disasters;
- disputes concerning our intellectual property or other proprietary rights;
- litigation or the threat of litigation;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- healthcare reform measures in the United States or other countries;
- sales of our common stock by our officers, directors or significant stockholders;

- future sales or issuances of equity or debt securities by us;
- fluctuations in our quarterly operating results; and
- the issuance of new or changed securities analysts' reports or recommendations regarding us.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

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

As of June 30, 2017 our executive officers, directors, and their respective affiliates beneficially owned approximately 7% of our outstanding voting stock. Accordingly, these stockholders may continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

***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 in the JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply 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 cannot predict if investors will find our common stock less attractive because we may 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. Based on our non-affiliated market capitalization as of June 30, 2017, we will cease to be an emerging growth company on January 1, 2018.

In addition, Section 102 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An "emerging growth company" can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

***Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. For example, on April 7, 2015, we filed a Registration Statement on Form S-3 (the "2015 Shelf Registration Statement"), covering the offering of up to \$150 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units. The 2015 Shelf Registration Statement included a prospectus covering the offering, issuance and sale of up to \$30.0 million of shares of our common stock from time to time in "at the market" ("ATM") offerings pursuant to a Common Stock Sales Agreement entered into with Cowen and Company, LLC (the "Sales Agreement") on April 7, 2015. Through June 30, 2017, we have sold 1,105,549 shares of common stock under the Sales Agreement, at a weighted-average price of approximately \$4.82 per share for aggregate gross proceeds of \$5.3 million.

On December 19, 2016, we completed an underwritten public offering of 7,475,000 shares of our common stock, at a price of \$13.50 per share, including the full exercise of the underwriters' option to purchase an additional 975,000 shares of common stock. We received net proceeds from the offering of \$94.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses. As of June 30, 2017, approximately \$43.8 million in securities remained unissued under the 2015 Shelf Registration Statement, including up to \$24.7 million of common stock available to be sold under the Sales Agreement, subject to certain conditions specified therein.

In addition, on May 31, 2017, we completed an underwritten public offering of 5,750,000 shares of our common stock, at a price of \$22.50 per share, including the full exercise of the underwriters' option to purchase an additional 750,000 shares of common stock on June 9, 2017. We received net proceeds from the offering of \$121.2 million, after deducting the underwriting discounts and commissions and offering expenses.

Any future debt financing may involve covenants that restrict our operations, including, among other restrictions, limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Further, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, including under our ATM, the issuance of these securities could result in further dilution to our stockholders or result in downward pressure on the price of our common stock.

***Future sales by our existing holders of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.***

If our existing stockholders or holders of our options or warrants sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of June 30, 2017, we have outstanding a total of 42,232,087 shares of common stock. Other than any shares held by our directors, officers and certain existing investors, all of these are currently freely tradable.

In addition, based on the number of shares subject to outstanding awards under our Amended and Restated 2003 Stock Plan (the "2003 Plan") or subject to outstanding awards or available for issuance under our 2014 Equity Incentive Award Plan (our "2014 Plan"), our 2014 Employment Commencement Incentive Plan (our "Inducement Plan") and our 2014 Employee Stock Purchase Plan (our "ESPP"), in each case, as of June 30, 2017, 6,769,424 shares of common stock that are either subject to outstanding awards, outstanding but subject to vesting, or reserved for future issuance under our 2003 Plan, 2014 Plan, Inducement Plan or ESPP will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. We have filed registration statements permitting shares of common stock issued in the future pursuant to the 2003 Plan, 2014 Plan, Inducement Plan or ESPP to be freely resold by plan participants in the public market and, for shares held by directors, executive officers and other affiliates, subject to compliance with Rule 144. The 2014 Plan and ESPP also contain a provision for the annual increase of the number of shares reserved for issuance under such plan, which shares we also intend to register in the future as such annual increases occurs. If the shares we may issue from time to time under the 2003 Plan, 2014 Plan, the Inducement Plan or ESPP are sold, or if it is perceived that they will be sold, by the award recipient in the public market, the trading price of our common stock could decline.

As of August 2, 2017, certain holders of 1,746,461 shares of our common stock, 407,331 shares of contingently redeemable common stock and warrants exercisable for 17,514 shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Sales of such shares could also cause the trading price of our common stock to decline.

***Provisions of our charter documents or Delaware law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change management.***

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

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director;
- a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;

- an advance notice requirement for stockholder proposals and nominations;
- directors may not be removed without cause and may only be removed with cause by the affirmative vote of 66 2/3% of all outstanding shares of our capital stock with the power to vote in the election of directors;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock with the power to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns or within the last three years has owned 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company. Furthermore, our amended and restated certificate of incorporation will specify that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

Provisions in our charter and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

***If we commit certain material breaches under the research agreement with the Gates Foundation, and fail to cure them, we may be required to redeem shares of our common stock held by the Gates Foundation and its affiliates.***

In the event of termination of the research agreement by the Gates Foundation for certain specified uncured material breaches by us, we will be obligated, among other remedies, to either redeem our common stock purchased by the Gates Foundation in connection with the research agreement, facilitate the purchase of such common stock by a third party or elect to register the resale of such common stock into the public markets unless certain specified conditions are satisfied. If we are required to redeem such shares of common stock, our financial condition could be materially and adversely affected.

***We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; as a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.***

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying any cash dividends on our capital 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. In addition, the terms of any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***If securities or industry analysts do not publish research, or publish inaccurate or 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. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

### ***(a) Recent Sales of Unregistered Equity Securities***

None.

*(b) Use of Proceeds*

None.

*(c) Issuer Purchases of Equity Securities*

Not applicable.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

**SIGNATURES**

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

Date: August 8, 2017

**ACHAOGEN, INC.**

By: /s/ Kenneth J. Hillan  
Kenneth J. Hillan, M.B., Ch. B.  
Chief Executive Officer  
**(principal executive officer)**

Date: August 8, 2017

By: /s/ Tobin C. Schilke  
Tobin C. Schilke  
Chief Financial Officer  
**(principal financial and accounting officer)**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Incorporated by Reference from</b>			<b>Provided Herewith</b>
		<b>Registrant's Form</b>	<b>File No.</b>	<b>Date Filed with the SEC</b>	
3.1	Amended and Restated Certificate of Incorporation of Achaogen, Inc.	8-K	001-36323	3/17/2014	3.1
3.2	Amended and Restated Bylaws of Achaogen, Inc.	8-K	001-36323	3/17/2014	3.2
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	333-193559	3/10/2014	4.1
4.3	Warrant issued to Oxford Finance LLC on November 1, 2011.	S-1	333-193559	1/24/2014	4.4
4.5	Warrant issued to Oxford Finance LLC on April 30, 2012 (Term A Loan (2)).	S-1	333-193559	1/24/2014	4.6
4.6	Warrant issued to Oxford Finance LLC on April 30, 2012 (Term B Loan).	S-1	333-193559	1/24/2014	4.7
4.7	Form of Warrant, issued pursuant to the Securities Purchase Agreement, dated June 1, 2016, by and among Achaogen, Inc. and the purchasers named therein.	S-3	333-212253	6/24/2016	4.3
10.1†	Letter Agreement by and between the Bill & Melinda Gates Foundation and the Company, dated May 4, 2017.				X
10.2†	Modification 0027, dated May 4, 2017, to Contract Award issued by the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services, dated August 30, 2010				X
10.3	First Amendment to Lease, dated April 7, 2017, by and between AP3-SF2 CT South, LLC and Achaogen, Inc.				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

\* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Achaogen, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

May 4, 2017  
Achaogen, Inc.  
One Tower Place, Suite 300  
South San Francisco, CA 94080  
Attention: Chief Executive Officer

Re: Strategic Relationship between the Bill & Melinda Gates Foundation and Achaogen, Inc.

Ladies and Gentlemen:

This letter agreement (including all appendices and attachments hereto, the “ **Letter Agreement** ”) is entered into in connection with the investment by the Bill & Melinda Gates Foundation (the “ **Foundation** ”), a Washington charitable trust that is a tax-exempt private foundation, of ten million dollars (\$10,000,000.00) (the “ **Foundation Investment** ”) in Common Stock of Achaogen, Inc. (the “ **Company** ”) at a purchase price of \$24.55 per share in accordance with the terms of a Common Stock Purchase Agreement dated May 4, 2017 (the “ **Purchase Agreement** ”). The Foundation Investment will be made in accordance with the provisions of the Purchase Agreement and this Letter Agreement (collectively, and together with any additional agreements that may be executed in connection with the Foundation Investment, in each case as amended from time to time in accordance with their terms, the “ **Investment Documents** ”). The Foundation Investment is conditioned upon the execution and delivery of the applicable Investment Documents by the parties thereto and the Foundation obtaining a written legal opinion from tax counsel that the Foundation Investment will qualify as a program-related investment under the Code.

In consideration of the Foundation making the Foundation Investment on the terms and conditions stated herein and in the Investment Documents, and for other good and valuable consideration, the parties hereto hereby irrevocably agree as follows:

**1. Definitions.** For the purposes of this Letter Agreement the following terms have the meanings indicated.

“ **Affiliate** ” means, as to any person or entity, any person or entity that, directly or indirectly, controls, is controlled by or is under common control with such person or entity at any time and for so long as that control exists, where “control” (for purposes of this definition of “Affiliate” only) means having the decision-making authority as to the person or entity and, further, where that control will be presumed to exist where a person or entity owns more than 50% of the equity (or that lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) entitled to vote regarding composition of the board of directors or other body entitled to direct the affairs of the person or entity.

“ **Background Intellectual Property** ” means any intellectual property either (a) owned or controlled by the Company prior to the execution of this Letter Agreement or (b) developed or

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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acquired by the Company independently from the performance of the Global Access Commitments.

“ **Charitability Default** ” has the meaning given in Section 5(b).

“ **Charitable Purpose** ” has the meaning given in Section 2(a)

“ **Claim** ” has the meaning given in Section 13.

“ **Code** ” means the U.S. Internal Revenue Code of 1986, as amended.

“ **COGS** ” means the Company’s cost of development, production, supply and distribution of a product determined in accordance with the Company’s usual and customary accounting methods, which are in accordance with GAAP; provided, that [\*\*\*], as provided to the Company.

“ **Common Stock** ” means shares of the Company’s common stock, par value \$0.001 per share and any securities issued as a dividend or other distribution with respect to, or in exchange for or in replacement of, such common stock.

“ **Company** ” has the meaning given in the introductory paragraph.

“ **Default Notice** ” has the meaning given in Section 5(c).

“ **Developing Countries** ” means those countries described on Appendix 1.

“ **Direct Competitor** ” means any entity that [\*\*\*]; provided, however, that (a) [\*\*\*] will not be considered a Direct Competitor unless such entity [\*\*\*] and (b) [\*\*\*] will not be considered Direct Competitors unless such entities [\*\*\*]. For the avoidance of doubt, neither [\*\*\*] is currently considered a Direct Competitor.

“ **Discovery Project** ” has the meaning given in Section 3(c)(i).

“ **Exchange Act** ” means the Securities Exchange Act of 1934, as amended.

“ **Fair Market Value** ” means (a) if the Common Stock is Freely Tradable, the closing price of the Common Stock on the primary U.S. securities exchange on which the stock trades on the most recent day such exchange was open for trading prior to the closing date of the redemption or purchase under Section 5 below or (b) if the Common Stock is not Freely Tradable, the then current fair market value of the Foundation Stock as determined by a mutually agreed upon (such agreement not to be unreasonably withheld, conditioned or delayed) independent third-party appraiser.

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

“ **Foundation-supported Entity** ” means an entity that receives funding, directly or indirectly, from the Foundation, collaborates with the Foundation, or both, for the purpose of accomplishing the Foundation’s charitable objectives.

“ **Foundation** ” has the meaning given in the introductory paragraph.

“ **Foundation Investment** ” has the meaning given in the introductory paragraph.

“ **Foundation Stock** ” has the meaning given in Section 5(c).

“ **Freely Tradable** ” means that the Common Stock is a class of securities registered under Section 12 (or any successor provision) of the Exchange Act, is not subject to restrictions from trading under the Securities Act or state securities laws and is listed on a U.S. national securities exchange and the Company is current in its filings with the SEC.

“ **Funded Developments** ” means the products, technologies, materials, software, and other intellectual property and intellectual property rights [\*\*\*] or [\*\*\*].

“ **Global Access** ” means (a) knowledge gained using the Foundation’s funding is promptly and broadly disseminated and (b) the products developed with the Foundation’s funding and owned, controlled or in licensed by the Company be made available and accessible at reasonable cost to people most in need in Developing Countries. For the avoidance of doubt, nothing in this Letter Agreement will prevent Company from reasonably developing or commercializing identical or similar products and technologies in Developing Countries for people who are not the focus of the Global Access Commitments unless there is no reasonable way of separating commercialization or distribution for low income versus non-low income individuals.

“ **Global Access Commitments** ” has the meaning given in Section 3.

“ **Global Health License** ” has the meaning given in Section 3(i)(i).

“ **Indemnitees** ” has the meaning given in Section 13.

“ **Investment Documents** ” has the meaning given in the introductory paragraph.

“ **Letter Agreement** ” has the meaning given in the introductory paragraph.

“ **License Trigger Event** ” has the meaning given in Section 3(i)(ii).

[\*\*\*].

“ **Minimum Purchase Price** ” means a price per share of the Foundation Stock equal to the price per share paid by the Foundation for the Foundation Stock pursuant to the Purchase Agreement (as adjusted for any stock split, stock dividend, combination, or other recapitalization or

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

re classification effected after the date hereof), plus a compounded annual return of 5% per annum from the date of issuance of the Foundation Stock until through the date of redemption or purchase.

“ **Neonatal Sepsis Program** ” has the meaning given in Section 3(b)(i).

“ **Neonatal Sepsis Product** ” has the meaning given in Section 3(b)(i).

“ **Platform Development Program** ” has the meaning given in Section 3(a).

“ **Platform Technology** ” means the Company’s [\*\*\*], whether existing at closing of the Foundation Investment or [\*\*\*].

“ **Product** ” means any drug, therapeutic, vaccine, diagnostic, or prophylactic developed pursuant to a Program.

“ **Program** ” means the Platform Development Program, the Neonatal Sepsis Program, and any Discovery Project (if applicable), and any other project funded by the Foundation, including through a grant, contract or program-related investment (if applicable).

“ **Progress Review Group** ” has the meaning given in Section 3(f).

“ **Purchase Agreement** ” has the meaning given in the introductory paragraph.

“ **Sale Transaction** ” means (a) the acquisition, directly or indirectly, after the date of this Letter Agreement, by any person or group (within the meaning of Section 13(d)(3) of the Exchange Act) of beneficial ownership of securities of the Company possessing more than 50% of the total combined voting power of all outstanding voting securities of the Company, (b) a merger, consolidation or other similar transaction involving the Company, except for a transaction in which the holders of the outstanding voting securities of the Company immediately prior to such merger, consolidation or other transaction hold, in the aggregate, securities possessing more than 50% of the total combined voting power of all outstanding voting securities of the surviving entity immediately after such merger, consolidation or other transaction, or (c) an assignment, sale, transfer or exclusive license of all or substantially all of the Company’s assets, whether by merger, stock transfer, or otherwise.

“ **SEC** ” means the Securities and Exchange Commission.

“ **Securities Act** ” means the Securities Act of 1933, as amended.

“ **TPM** ” has the meaning given in Section 3(b)(ii).

“ **TPP** ” means a target product profile.

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

“ **Withdrawal Right** ” has the meaning given in Section 5(c).

## **2. Charitable Purposes and Use of Funds .**

(a) The Foundation is making the Foundation Investment as a “program-related investment” within the meaning of Section 4944(c) of the Code. The Foundation is making the Foundation Investment to gain access to Company’s proprietary technology for its global health purposes and to accelerate the Company’s Neonatal Sepsis Program, including inducing the Company to perform the Global Access Commitments set forth herein. The Company acknowledges and agrees that it would not undertake the Global Access Commitments as detailed herein absent the Foundation Investment. The Foundation’s primary purpose in making the Foundation Investment is to further significantly the accomplishment of the Foundation’s charitable purposes, including the relief of the poor, distressed, and underprivileged, the advancement of science, and the promotion of health by seeking to secure Global Access to new, low-cost drugs (both therapeutics and prophylactics) developed (in whole or in part) through the use of the Platform Technology and directed at pathogens that disproportionately affect people in Developing Countries (collectively, the “ **Charitable Purpose** ”). In furtherance of the Charitable Purpose, the Foundation Investment will secure the Global Access Commitments described below.

(b) The proceeds from the Foundation Investment will be used solely to (i) conduct the Platform Development Program and (ii) establish the capabilities necessary to conduct the Neonatal Sepsis Program and any Discovery Projects.

The proceeds from the Foundation Investment will not be required to be segregated in a separate account nor required to be used for dedicated employees or facilities.

## **3. Global Access Commitments .**

In furtherance of the Charitable Purpose and Global Access, the Company agrees to the following (the provisions of this Section 3, together with the provisions of Section 6, the “ **Global Access Commitments** ”):

(a) **Platform Development Program** . The Company will diligently conduct (i) the development and scale-up of the Platform Technology and (ii) in connection with such development and scale-up, the application of the Platform Technology to the identification of [\*\*\*], potentially in collaboration with other Foundation-supported Entities, as appropriate, in accordance with the scope of work set forth in Appendix 2 (the “ **Platform Development Program** ”).

### **(b) Neonatal Sepsis Program .**

(i) The Company will diligently conduct research, development, and use of the Platform Technology to develop and launch a product(s) (“ **Neonatal Sepsis Product** ”), either consisting of [\*\*\*], for the prevention and/or treatment of key pathogens that cause

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

neonatal sepsis in Developing Countries in accordance with one or more TPPs (“ **Neonatal Sepsis Program** ”). The TPP for the initially-contemplated prophylactic combination of [\*\*\*] will be mutually agreed by the parties within [\*\*\*] following the closing of the Foundation Investment. The Foundation may elect to include additional TPPs for other [\*\*\*] in the Neonatal Sepsis Program, which TPPs would be subject to the mutual agreement of the parties.

(ii) The work on the Neonatal Sepsis Program (which would be co-funded by separate grants from the Foundation pursuant to the Foundation’s standard grant making terms and processes or a Foundation-supported Entity, except to the extent certain portions of the work are already covered by the Platform Development Program and subject to the allocation referenced below) will include applicable research, development, launch and associated activities conducted by the Company, and the progression through completion of clinical studies by the Company demonstrating the Neonatal Sepsis Product’s safety/tolerability and efficacy and launch in the Developing Countries, if and to the extent these activities are requested by the Foundation. If the Foundation determines during the development process that working with a third-party manufacturer (“ **TPM** ”) is [\*\*\*], the Company [\*\*\*] in order to allow the production of the Neonatal Sepsis Product for the Developing Countries. The Company will have the right to veto the Foundation’s nomination of a TPM [\*\*\*] if the Company reasonably believes such TPM is a Direct Competitor. Such veto will not prohibit the Foundation from working with the TPM, [\*\*\*]. For the avoidance of doubt, the veto [\*\*\*]. If the Company vetos a proposed TPM, [\*\*\*]. If a TPM is a Direct Competitor and the Foundation [\*\*\*] from such TPM in a product being developed under the Neonatal Sepsis Program [\*\*\*], the Company and the Foundation [\*\*\*] in order to continue development of such product in an efficient manner [\*\*\*].

(iii) The Company will conduct the Neonatal Sepsis Program in accordance with the Foundation’s standard grant agreements and grant making process. The grant agreements for the Neonatal Sepsis Program will include a proposal describing the relevant work and other related documents acceptable to the Foundation, and will include the TPP, once developed by the parties. The grant agreements will also include [\*\*\*] resulting from the Neonatal Sepsis Program. The Foundation [\*\*\*], to [\*\*\*] to advance the Neonatal Sepsis Product through launch of a final product. The specific [\*\*\*] for the Neonatal Sepsis Program [\*\*\*] Developing Countries and developed countries.

**(c) Discovery Projects .**

(i) In addition to the Platform Development Program and Neonatal Sepsis Program, the Company will utilize the Platform Technology to diligently conduct up to [\*\*\*] proposed by the Foundation or a Foundation-supported Entity and conducted by the Company utilizing the Platform Technology [\*\*\*] (each such project, a “ **Discovery Project** ”) [\*\*\*] and subject to the terms below. Discovery Projects must be reasonably related to Company’s ongoing research and development activities. Should a Discovery Project not be reasonably related, the Company agrees to [\*\*\*] negotiate and develop a mutually agreed workplan.

(ii) Each Discovery Project will be funded and conducted pursuant to the Foundation’s standard grant agreement and grant making process, which would include a

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

proposal prepared by the Company (which will be submitted within [\*\*\*] days after the Foundation's initial request to the Company) describing the relevant work to be conducted by the Company and other related documents acceptable to the Foundation. The parties will negotiate, as part of any such grant agreements, [\*\*\*] resulting from the applicable Discovery Project. If the Foundation requests that the Company continue development of a candidate identified through a Discovery Project, the Company will consider in good faith and the parties will negotiate in good faith the terms of the applicable grant proposal for such work. To the extent a Discovery Project is funded beyond the discovery phase, the specific level and allocation of additional funding responsibilities for such Discovery Project will be [\*\*\*] to fairly allocate the expected benefits between Developing Countries and developed countries.

(d) **Intellectual Property of Third Parties** . The Foundation's investment will be conditioned on the Company's receipt and continuation of all necessary licenses and rights with respect to the Platform Technology needed to perform the Global Access Commitments. To the extent that a [\*\*\*] of the Neonatal Sepsis Product [\*\*\*], the Company will [\*\*\*], in order to enable completion of the applicable Product in accordance with the Global Access Commitments, [\*\*\*]. The Foundation will be [\*\*\*] to the extent necessary for the Product in Developing Countries; provided, that the [\*\*\*] before the [\*\*\*] and the terms allow the [\*\*\*].

(e) [\*\*\*]. The Company will work with the Foundation to develop [\*\*\*] and execute a manufacturing and supply plan that will enable the Company to meet the reasonably expected demand in Developing Countries for the Neonatal Sepsis Product and any Products developed under Discovery Projects. The expected demand will be determined by the Foundation and the Company based upon review of [\*\*\*]. The price of the relevant Products in Developing Countries will be such that the products are affordable to low income individuals in the Developing Countries, [\*\*\*]. The manufacturing and supply plan could involve the use of manufacturing partners and support from donors, and the specific level and allocation of funding responsibilities in such plan will be decided as [\*\*\*] Developing Countries and developed countries. The Foundation will have the [\*\*\*]. [\*\*\*].

(f) **Progress Review Group** . The Company and the Foundation will each designate no fewer than two and no more than three individuals to be part of a progress review group (the “ **Progress Review Group** ”) that will provide a forum for discussion of the progress of Programs. The Progress Review Group will meet at least once quarterly via teleconference and at least once annually in-person. With the agreement of both parties and subject to the execution of appropriate confidentiality agreements, third parties may be invited from time to time to participate in certain Progress Review Group discussions.

(g) **Publication** . The Company will (in addition to the publication requirements of any applicable grants from the Foundation):

(i) publish the results and information developed in connection with the Neonatal Sepsis Program (including the pre-clinical program) and any Discovery Project within a reasonable period of time after such information or results are obtained, subject to reasonable

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

delays or limitations on content of such publications that are necessary to protect intellectual property and trade secrets covering the Platform Technology itself;

(ii) promptly provide from time to time, upon the Foundation's reasonable request and with the agreement of the relevant Foundation-supported Entity (as appropriate), access to data and information regarding the Neonatal Sepsis Program and any Discovery Project, and the reasonably contemplated use of the Platform Technology for such programs; and

(iii) promptly provide to the Foundation from time to time, upon the Foundation's request, rights to share such data and information regarding the Neonatal Sepsis Program and any Discovery Project, and the reasonably contemplated use of the Platform Technology for such programs, subject to the reasonable need to protect confidential information and to avoid untimely public disclosures that may bar access to patent protection or public disclosures that may undermine trade secret protection.

All publications must be made in accordance with "open access" terms and conditions consistent with the Foundation's Open Access Policy available at: <http://www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy>, which may be modified from time to time.

(h) **No Inconsistent Rights** . Company will not grant to a third party any rights or enter into any arrangements or agreements that would limit or restrict the Foundation's rights to the Global Access Commitments, including the Foundation's right to enter into then currently-pending or proposed Discovery Projects with the Company.

(i) **Global Health License** .

(i) **Global Health License** . Subject to Section 3(i)(ii), in connection with and relating to the Neonatal Sepsis Program and each Discovery Project (if applicable), the Company hereby grants the Foundation and/or Foundation-supported Entities, [\*\*\*], non-exclusive, [\*\*\*] to the (A) Funded Developments and (B) the necessary Background Technology that covers or is used in the Platform Technology or applicable programs [\*\*\*] directed at pathogens that disproportionately affect people in Developing Countries and in a manner consistent with the Charitable Purpose (the "**Global Health License**"). Components of the Company's Background Intellectual Property will be subject to the Global Health License only to the extent and only for so long as they are necessary to reasonably achieve the development or disposition of an existing Program, Product or service. The grant agreements with respect to the Neonatal Sepsis Program and any Discovery Project will include license provisions consistent with the license provisions set forth in this Letter Agreement.

(ii) **License Trigger Events** . The Global Health License is presently granted and effective. However, the Foundation will not exercise its rights under the Global Health License [\*\*\*] unless a License Trigger Event occurs. In the event of a License Trigger Event that applies only to a particular Product or Program, the Foundation will have the right to

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

exercise the Global Health License only for such Product or Program. “ **License Trigger Event** ” means:

(A) a Charitability Default; or

(B) the Company (i) institutes any bankruptcy, insolvency, appointment of a receiver and/or trustee or reorganization (in either case for the release of financially distressed debtors), general assignment for the benefit of creditors, winding-up, dissolution, liquidation or similar proceeding relating to it under the laws of any jurisdiction or any such proceeding is instituted against the Company which remains undismissed or unstayed for a period of [\*\*\*] days or (ii) ceases to conduct business in the ordinary course.

If either the Foundation or the Company becomes aware of a License Trigger Event, it will promptly notify the other party in writing of the occurrence of a License Trigger Event.

(j) **Cooperation; Technology Transfer** . In the event of a License Trigger Event, the Company will take further actions, including technology transfer (subject to the transferee agreeing to appropriate confidentiality obligations), as would be [\*\*\*], to accommodate that the Foundation, [\*\*\*], and/or the relevant Foundation-supported Entity can effectively exercise the applicable Global Health License and use the related technology if a License Trigger Event occurs (including the right to reference regulatory filings related to the applicable products).

(k) **Duration of Global Access Commitments** . The Global Access Commitments will be ongoing and will continue for the earlier of (i) 25 years following the closing of the Foundation Investment or (ii) seven years following the termination of all Foundation or Foundation-supported Entity funding of Company programs and projects; provided, that in the event a Product or service developed (in whole or in part) with Foundation funding continues to be developed or available in Developing Countries, the Global Access Commitments will be ongoing and will continue with respect to such Product or service. Notwithstanding the foregoing, [\*\*\*].

(l) [\*\*\*]. The Company represents and covenants that the Company has and will continue to have [\*\*\*] and [\*\*\*].

#### 4. [\*\*\*] **Global Access Commitments** .

In the event of (i) [\*\*\*], or (ii) [\*\*\*], the Global Access Commitments [\*\*\*]. The Foundation will have the right to review [\*\*\*] of the Global Access Commitments to confirm that the Global Access Commitments [\*\*\*] and [\*\*\*] by the acquirer and continue to [\*\*\*] by the Foundation. For clarity, notwithstanding anything to the contrary in this Letter Agreement, [\*\*\*].

#### 5. **Withdrawal Right** .

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

(a) The Withdrawal Right described and defined in this Section 5 will be triggered only as a result of a Charitability Default.

(b) A “ **Charitability Default** ” will occur if the Company (i) is in material breach of the Global Access Commitments, including the failure to conduct the Programs as described above, other than for reasons of technical or scientific failure not known to the Company at or before closing of the Foundation Investment, (ii) fails to comply with the restrictions in Sections 2 and 8 of this Letter Agreement on the use of proceeds from the Foundation Investment, or (iii) fails to comply with the other related U.S. legal obligations set forth in this Letter Agreement, including, the requirements set forth in Sections 6, 8, 9, 10, and 11. Each party agrees to promptly notify the other party in writing if it becomes aware of any Charitability Default and the Company will thereafter promptly provide to the Foundation a proposed strategy to remedy the Charitability Default. Notwithstanding the foregoing, the Foundation will not lose any rights or remedies solely as a result of a failure to notify the Company after it becomes aware of a Charitability Default.

(c) If the Company fails to cure the Charitability Default within [\*\*\*] days of the delivery to the Company of the Foundation’s written notice of such Charitability Default (the “ **Default Notice** ”), and if the Foundation holds any securities of the Company issued in connection with the Foundation Investment, including securities issued in respect of or upon conversion or exercise of such securities (collectively, the “ **Foundation Stock** ”), the Company will have the obligation, if irrevocably requested in writing by the Foundation not later than [\*\*\*] days after the delivery of the Default Notice to the Company, to either (i) redeem all of the Foundation Stock at a price per share equal to the greater of the Minimum Purchase Price or the Fair Market Value; provided, that such redemption will be made only to the extent permitted by applicable law concerning distributions to holders of equity interests in the Company and not to the extent that it renders the Company insolvent, (ii) facilitate the purchase of the Foundation Stock to one or more buyers at a price per share equal to the greater of the Minimum Purchase Price or the Fair Market Value, or (iii) if the Foundation Stock is not Freely Tradeable, register the resale of the Foundation Stock on an effective registration statement and keep such registration statement continuously effective until the earlier of (x) the date all Foundation Stock has been sold and (y) the date that is [\*\*\*] following the effective date of the registration statement ((i), (ii), and (iii) the “ **Withdrawal Right** ”). If the Company is unable to redeem all of the Foundation Stock, and no third party purchases the Foundation Stock, then the Company will [\*\*\*], consistent with the Code and applicable law, [\*\*\*].

(d) Notwithstanding the foregoing, if the Company elects to satisfy the Withdrawal Right pursuant to clauses 5(c) (ii) or (iii) above, and the Foundation receives less than the Minimum Purchase Price per share, then the Company will [\*\*\*]. Notwithstanding any exercise of the Withdrawal Right by the Foundation, the Foundation will continue to be entitled to enforce its rights under the Global Access Commitments.

## **6. Required Reporting; Audit Rights.**

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

(a) In addition to reports required to be delivered to the Foundation under the Investment Documents, the Company will furnish, or cause to be furnished, to the Foundation the following reports and certifications:

(i) within [\*\*\*] days after the end of each of the Company's fiscal years during which the Foundation owns any Foundation Stock, a certificate from the Company signed by an officer or director of the Company and substantially in the form attached to this Letter Agreement as Appendix 3, certifying that the requirements of the Foundation Investment set forth in this Letter Agreement were met during the immediately preceding fiscal year, describing the use of the proceeds of the Foundation Investment and evaluating the Company's progress toward achieving the Global Access Commitments;

(ii) within [\*\*\*] days after the end of the Company's fiscal year during which the Foundation ceases to own any Foundation Stock, a certificate from the Company signed by an officer or director of the Company and substantially in the form attached to this Letter Agreement as Appendix 4, certifying that the requirements of the Foundation Investment set forth in this Letter Agreement were met during the time that the Foundation held the Foundation Stock, describing the use of the proceeds of the Foundation Investment and evaluating the Company's progress toward achieving the Global Access Commitments;

(iii) any other information respecting the operations, activities and financial condition of the Company as the Foundation may from time to time reasonably request to discharge any expenditure responsibility, within the meaning of Sections 4945(d)(4) and 4945(h) of the Code, of the Foundation with respect to the Foundation Investment, and to otherwise monitor the charitable benefits intended to be served by the Foundation Investment. The Foundation will reimburse the Company for any reasonable third-party expenses incurred by the Company in order to prepare any information the Company is required to prepare solely as a result of this Section 6(a)(iii); and

(iv) full and complete financial reports of the type ordinarily required by commercial investors under similar circumstances to the extent required pursuant to Treasury Regulation 53.4945-5(b)(4); *provided*, that so long as the Company is a reporting company under the Exchange Act, the filing of quarterly and annual reports with the SEC will be deemed to satisfy the obligations of this Section 6(a)(iv).

(b) At the Foundation's reasonable request and at reasonable times and intervals, the Company will provide the Foundation with the following:

(i) a summary of scientific data and progress on all Programs; and

(ii) a report to the reasonable satisfaction of the Foundation detailing the progress and data through clinical studies designed to assess the Neonatal Sepsis Product's (and any other Product's) human safety/tolerability and efficacy, and certifying what costs and expenses the Company has incurred for the each Program to date, and the considerations made

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by the Company with respect to accessibility, affordability and cost effectiveness of the Neonatal Sepsis Product (and any other Products) for people and payors in Developing Countries.

(c) Without limiting the foregoing, the Company will permit the Foundation or its representatives to inspect (at a reasonable time and location) the scientific records of the Company relating to each Program with due regard to the reasonable need to protect trade secrets covering the Platform Technology.

(d) The Company will maintain books and records adequate to provide information ordinarily required by commercial investors under similar circumstances, including accounting records and copies of any reports submitted to the Foundation related to each Program. The Company will retain such books, records, and reports for [\*\*\*] after the Foundation ceases to hold Company securities and will make such books, records and reports available to the Foundation at reasonable times to enable the Foundation to monitor and evaluate how the Foundation's funds have been used.

(e) The Company agrees to permit employees or agents of the Foundation, all of whom are bound by written confidentiality obligations or policies substantially similar to the Foundation's obligations under the Nondisclosure Agreement between the parties dated effective as of February 8, 2017, at any reasonable time and upon reasonable prior notice, during normal business hours, to examine or audit the Company's relevant books and accounts of record and to make copies and memoranda of the same, in each case at the Foundation's expense to audit the Company's compliance with the use of the Foundation Investment and the Global Access Commitments; provided, that (i) the Foundation will not conduct such an examination or audit more frequently than [\*\*\*] unless required due to any audit, request or inquiry of the Foundation by the Internal Revenue Service or because the Company previously materially failed such an [\*\*\*] audit and (ii) the Company shall not be obligated to grant access to materials covered by attorney-client privilege. If the Company maintains any relevant records (including computer generated records and computer software programs for the generation of such records) in the possession of a third party, the Company, upon request of the Foundation, will notify such party to permit the Foundation free access to such records at all reasonable times and to provide the Foundation with copies of any records it may reasonably request in connection with such audit, request or inquiry, all at the Foundation's expense.

## **7. Assignment**

Notwithstanding anything in this Letter Agreement to the contrary, the Foundation will have the right to assign this Letter Agreement or transfer the Foundation Stock to (a) any successor charitable organization of the Foundation from time to time that is a tax exempt organization as described in Section 501(c)(3) of the Code, or (b) any tax exempt organization as described in Section 501(c)(3) of the Code controlled by one or more trustees of the Foundation. The Foundation will notify the Company of any such assignment, including the identity of the assignee, in a timely manner. For the avoidance of doubt, if the Foundation transfers the Foundation Stock as permitted by this Section 7, the Foundation may assign to any such transferee all of its rights attached to such Foundation Stock, including the Withdrawal Right.

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**8. Prohibited Uses**

The Company will not expend any proceeds of the Foundation Investment to carry on propaganda or otherwise to attempt to influence legislation, to influence the outcome of any specific public election or to carry on, directly or indirectly, any voter registration drive, or to participate or intervene in any political campaign on behalf of or in opposition to any candidate for public office within the meaning of Section 4945(d) of the Code. The proceeds of the Foundation Investment will not (a) be earmarked to be used for any activity, appearance or communication associated with the activities described in the foregoing sentence, nor (b) be intended for the direct benefit of, and will not benefit, any person having a personal or private interest in the Foundation, including descendants of the founders of the Foundation, or persons related to or controlled by, directly or indirectly, such private interests.

For the avoidance of doubt, the Company will not use the funds received from the Foundation to pay a dividend or redeem shares.

**9. Disqualified Person**

Neither the Company nor (to the best knowledge of the Company) any stockholder of the Company is a “disqualified person” with respect to the Foundation (as the term “disqualified person” is defined in Section 4946(a) of the Code). The Foundation does not, and one or more disqualified persons with respect to the Foundation do not, directly or indirectly, control the Company. With respect to “knowledge” of the Company, such representation is based solely on a review of the SEC filings made by third parties as required under the U.S. securities laws and the stock records of its transfer agent as of the most recent practicable date prior to entry into this Letter Agreement.

**10. Anti-Terrorism**

The Company will not use any portion of the Foundation Investment, directly or indirectly, in support of activities (a) prohibited by U.S. laws related to combatting terrorism; (b) with persons on the List of Specially Designated Nationals ([www.treasury.gov/sdn](http://www.treasury.gov/sdn)) or entities owned or controlled by such persons; or (c) with countries or territories against which the U.S. maintains a comprehensive sanctions embargo (currently, Cuba, Iran, (North) Sudan, Syria, North Korea, and the Crimean Region of Ukraine), unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

**11. Anti-Corruption and Anti-Bribery**

The Company will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or any activities contemplated by this Letter Agreement or the Company’s organizational documents (e.g., certificate of incorporation), including by assisting any party to secure an unlawful advantage. Training and information on compliance with these requirements

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are available at [www.learnfoundationlaw.org](http://www.learnfoundationlaw.org) .

## **12. Public Reports; Use of Name .**

Following the closing of the Foundation Investment, each party may publicly disclose the fact that the Foundation has made the Foundation Investment, the amount of the Foundation Investment, and the establishment of the Platform Development Program and Neonatal Sepsis Program. The Foundation and the Company may also include information on this investment in its periodic public reports and to the extent required by applicable law or regulation. Any other announcement of the Foundation Investment by or on behalf of the Company or the Foundation will require the prior written approval of the other party. Neither party's name and logo will be used by the other party in any manner to market, sell or otherwise promote such party, its products, services and/or business without the prior written consent of the other party. Nothing in this Section 12 prohibits the Company from disclosing the Investment Documents, the transactions contemplated therein, or the Foundation's identity and participation to the extent such disclosure is required by applicable laws, regulations or stock exchange requirements. In the event of a conflict between this Section 12 and the terms and conditions of any grant agreement between the parties, this Section 12 will control.

## **13. Indemnification .**

The Company will indemnify, hold harmless, and defend the Foundation and its co-chairs, trustees, directors, officers, employees, agents, and representatives (collectively, the “**Indemnitees**”) from and against any and all third party causes of action, claims, suits, legal proceedings, judgments, settlements, damages, penalties, losses, liabilities and costs (including reasonable attorneys' fees and costs) (each a “**Claim**”) finally awarded to such third party by a court of competent jurisdiction against any of the Indemnitees or agreed to as part of a monetary settlement of the Claim and arising out of or relating to: [\*\*\*]. The Foundation will give the Company prompt written notice of any Claim subject to indemnification; provided, that the Foundation's failure to promptly notify the Company will not affect the Company's indemnification obligations except to the extent that the Foundation's delay prejudices the Company's ability to defend the Claim. The Company will have sole control over the defense and settlement of each and every Claim, with counsel of its own choosing which is reasonably acceptable to the Foundation; provided, that the Company conducts the defense actively and diligently at the sole cost and expense of the Company and provided further that the Company will not enter into any settlement that adversely affects any Indemnitee without the applicable Indemnitee's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. The Foundation will provide the Company, upon request, with reasonable cooperation in connection with the defense and settlement of the Claim. Subject to the Company's rights above to control the defense and settlement of Claims, the Foundation and any Indemnitee may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim under this Section 13. The Company shall not have any liability or obligations with respect to any Claim under this Section 13 to the extent such Claim results from an Indemnitee's fraud, negligence, gross negligence or willful misconduct.

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The parties will not be liable to each other for any indirect, incidental, consequential, or special damages (including lost revenues, lost savings, or lost profits suffered by such other party) suffered by such other party arising under or in connection with this Letter Agreement, regardless of the form of action, whether in contract or tort, including negligence of any kind whether active or passive, and regardless of whether the party knew of the possibility that such damages could result; provided, that to the extent an Indemnitee is entitled to be indemnified hereunder for Claims of third parties and such third party has been awarded indirect, incidental, consequential, reliance, or special damages (including lost revenues, lost savings, or lost profits), the Company's indemnification obligations to the Indemnitee will extend to and include such third party's indirect, incidental, consequential, reliance, or special damages (including lost revenues, lost savings, or lost profits). The parties further agree that under no circumstances will any party be liable to the other party (or to any Indemnitee) more than once for the same losses arising under or in connection with this Letter Agreement.

#### **14. Insurance.**

The Company agrees to maintain insurance coverage [\*\*\*]. The Company will ensure all subcontractors maintain insurance coverage consistent with this paragraph.

#### **15. Compliance with Laws and Requirements; Responsibility.**

The Company agrees to comply with all applicable laws and regulations, including intellectual property laws in connection with the performance of its obligations under this Letter Agreement. The Company will conduct, control, manage, and monitor the Programs in compliance with all applicable ethical, legal, regulatory, and safety requirements, including applicable international, national, local, and institutional standards (“**Requirements**”). The Company will obtain and maintain all necessary approvals, consents, and reviews before conducting the applicable activity. If the project involves:

(a) any protected information (including personally identifiable, protected health, or third party confidential), the Company will not disclose this information to the Foundation without obtaining the Foundation's prior written approval and all necessary consents to disclose such information;

(b) children or vulnerable subjects, the Company will obtain any necessary consents and approvals unique to these subjects; or

(c) any trial involving human subjects, the Company will adhere to current Good Clinical Practice as defined by the International Council on Harmonisation (ICH) E-6 Standards (or local regulations if more stringent) and applicable trial insurance will be obtained.

The Company will be solely responsible and liable for all activities related to the conduct of the Programs. For avoidance of doubt, as between the Foundation and the Company, the Company will have responsibility for all clinical trials. Any activities by the Foundation in reviewing

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documents and providing input or funding do not modify the Company's responsibility, including responsibility for determining and complying with the provisions of this Section 15.

**16. Entire Agreement; Modification**

The terms and conditions set forth in this Letter Agreement are in addition to the provisions stated in the other Investment Documents and the terms and conditions of this Letter Agreement will prevail over any inconsistent provision in any other Investment Document. No change, modification or waiver of any term or condition of this Letter Agreement will be valid unless it is in writing, it is signed by the party to be bound, and it expressly refers to this Letter Agreement. For avoidance of doubt, the terms of this Letter Agreement will not be deemed to supersede any provisions of the Unilateral Confidential Disclosure Agreement between the parties dated effective as of February 8, 2016 or the Nondisclosure Agreement between the parties dated effective as of February 8, 2017.

**17. Authority; Governing Law**

Each of the signatories below covenants, represents and warrants that he, she or it had all authority necessary to execute this Letter Agreement and that, on execution, this Letter Agreement will be fully binding and enforceable in accordance with its terms, and that no other consents or approvals of any other person or third parties are required or necessary for this Letter Agreement to be so binding. This Letter Agreement will be governed by the laws of the State of Delaware, excluding its conflicts of laws provisions.

**18. Counterparts**

This Letter Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which will be deemed to be and constitute one and the same instrument.

**19. Construction**

Section headings are not to be considered part of this Letter Agreement, are included solely for convenience, are not intended to be full or accurate descriptions of the content thereof, and will not effect the construction of this Letter Agreement. The words "include," "includes" and "including" will be considered to be followed by the words "without limitation".

Signature Page Follows

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

The parties have caused this Letter Agreement to be executed as of the date first set forth above.

**Achaogen, Inc.**

**Bill & Melinda Gates Foundation**

By: /s/ Kenneth Hillan  
Name: Kenneth Hillan  
Title: CEO

By: /s/ Jim Bromley  
Name: Jim Bromley  
Title: CFO

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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## Appendix 2

### Platform Development Program Scope of Work

[\*\*\*].

[\*\*\*]:

[\*\*\*]:

1. [\*\*\*];
2. [\*\*\*];
3. [\*\*\*];
4. [\*\*\*];
5. [\*\*\*];
6. [\*\*\*];
7. [\*\*\*];
8. [\*\*\*];
9. [\*\*\*].

*Scope of work for platform improvement:*

*Goals:*

1. [\*\*\*];
2. [\*\*\*];
3. [\*\*\*];
4. [\*\*\*].
5. [\*\*\*]
6. [\*\*\*]
7. [\*\*\*].
8. [\*\*\*]

*Steps:* In order to achieve these proposed goals, AKAO will take the corresponding steps:

1. [\*\*\*]
2. [\*\*\*]
3.
  - A. [\*\*\*]
  - B. [\*\*\*]
  - C. [\*\*\*]
4.
  - A. [\*\*\*]
  - B. [\*\*\*]
  - C. [\*\*\*]
5. [\*\*\*]
6. [\*\*\*]
7. [\*\*\*]

[\*\*\*].

**Aim 2:** Development of therapeutic mAb candidates

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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Confidential Treatment Requested by Achaogen Inc.

[\*\*\*]

[\*\*\*] :  
[\*\*\*].

[\*\*\*] :  
[\*\*\*].

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**Appendix 3**

**OFFICER'S/DIRECTOR'S CERTIFICATE**

**ACHAOGEN, INC.**

DATE

This certificate is being delivered by Achaogen, Inc. , a Delaware corporation (the “ Company ”), pursuant to Section 6(a)(i) of the Letter Agreement between the Company and the Bill & Melinda Gates Foundation dated as of May 4, 2017 (the “ Letter Agreement ”). Capitalized terms used but not otherwise defined herein have the meanings ascribed to them in the Letter Agreement.

The Company certifies as follows:

1. During the fiscal year ended DATE, the Company met the requirements of the Foundation Investment as set forth in the Letter Agreement that were required to be complied with or performed by the Company during such time period.

2. Attached as Exhibit A to this certificate is a description of the Company’s use of proceeds of the Foundation Investment during the fiscal year ended DATE.

3. Attached as Exhibit B to this certificate is the Company’s evaluation of the Company’s progress with respect to the Platform Development Program, Neonatal Sepsis Program, and any Discovery Project, including information regarding progress against the Global Access Commitments (as set forth in the Investment Documents) during the fiscal year ended DATE.

IN WITNESS WHEREOF, the undersigned has executed this certificate and has caused this certificate to be delivered on the date first above written.

Achaogen, Inc.

By: \_\_\_\_\_  
Name:  
Title:

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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**Appendix 4**

**OFFICER'S/DIRECTOR'S CERTIFICATE**

**ACHAOGEN, INC.**

DATE

This certificate is being delivered by Achaogen, Inc. , a Delaware corporation (the “ Company ”), pursuant to Section 6(a)(ii) of the Letter Agreement between the Company and the Bill & Melinda Gates Foundation dated as of May 4, 2017 (the “ Letter Agreement ”). Capitalized terms used but not otherwise defined herein have the meanings ascribed to them in the Letter Agreement.

The Company certifies as follows:

1. During the term of the Foundation Investment, the Company met the requirements of the Foundation Investment as set forth in the Letter Agreement that were required to be complied with or performed by the Company during such time period.

2. Attached as Exhibit A to this certificate is a description of the Company’s use of proceeds of the Foundation Investment during the term of the Foundation Investment.

3. Attached as Exhibit B to this certificate is the Company’s evaluation of the Company’s progress with respect to the Platform Development Program, Neonatal Sepsis Program, and any Discovery Project, including information regarding progress against the Global Access Commitments (as set forth in the Investment Documents) during the term of the Foundation Investment.

IN WITNESS WHEREOF, the undersigned has executed this certificate and has caused this certificate to be delivered on the date first above written.

Achaogen, Inc.

By: \_\_\_\_\_  
Name:  
Title:

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

Confidential Treatment Requested by Achaogen Inc

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE OF PAGES 1   2
2. AMENDMENT/MODIFICATION NO. 0027	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS195778	5. PROJECT NO. ( If applicable )
6. ISSUED BY CODE ASPR-BARDA ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	7. ADMINISTERED BY ( If other than Item 6 ) CODE ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201		ASPR-BARDA
8. NAME AND ADDRESS OF CONTRACTOR ( No., street, county, State and ZIP Code ) ACHAOGEN, INC. 1361331 ACHAOGEN, INC. 7000 SHORELINE 7000 SHORELINE CT STE 371 SOUTH SAN FRANCISCO CA 940801957		(X) 9A. AMENDMENT OF SOLICITATION NO.	
CODE 1361331 FACILITY CODE		X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201000046C	
		10B. DATED ( SEE ITEM 13 ) 09/01/2010	

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended  is not extended

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA ( If required )  
2017.1992017.25106 Net Increase: [\*\*\*]

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: ( Specify authority ) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES ( such as changes in paying office, appropriation date, etc. ) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER ( Specify type of modification and authority ) Bilateral: Mutual Agreement of the Parties and FAR Clause 52.217-7

E. IMPORTANT: Contractor  is not  is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION ( Organized by UCF section headings, including solicitation/contract subject matter where feasible. )

Tax ID Number: 68-0533693

DUNS Number: 167293153

The purpose of this modification is to obligate funds in the amount of [\*\*\*] to allow for additional Option 1/CLIN 2 costs incurred as a result of updated rates.

A. This modification hereby results in the following increase to the total contract funding:

1. The Total Estimated Cost of the contract is hereby increased by [\*\*\*], from [\*\*\*] to [\*\*\*].

2. The Total Fixed fee remains unchanged at [\*\*\*].  
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER ( Type or print ) T OBIN C. S CHILKE CFO		16A. NAME AND TITLE OF CONTRACTING OFFICER ( Type or print ) THOMAS P. HASTINGS	
15B. CONTRACTOR/OFFEROR /s/ Tobin C. Schilke ( Signature of person authorized to sign )	15C. DATE SIGNED 4/28/17	16B. UNITED STATES OF AMERICA /s/ Thomas P. Hastings ( Signature of Contracting Officer )	16C. DATE SIGNED 5/4/17

NSN 7540-01-152-8070  
Previous edition unusable

STANDARD FORM 30 (REV. 10-83)  
Prescribed by GSA  
FAR (48 CFR) 53.243

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

Confidential Treatment Requested by Achaogen Inc.

<b>CONTINUATION SHEET</b>	REFERENCE NO. OF DOCUMENT BEING CONTINUED HHSO100201000046C/0027	PAGE OF 2 2
NAME OF OFFEROR OR CONTRACTOR ACHAOGEN, INC. 1361331		

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
-----------------	--------------------------	-----------------	-------------	-------------------	---------------

3. The Total Estimated Cost Plus Fixed Fee is hereby increased by [\*\*\*], from [\*\*\*]to [\*\*\*].

B. All other terms and conditions of the contract remain unchanged.

Delivery: 05/16/2017  
 Delivery Location Code: HHS/OS/ASPR  
 HHS/OS/ASPR  
 200 C St SW  
 WASHINGTON DC 20201 US

Appr. Yr.: 2017 CAN: 1992017 Object Class: 25106  
 FOB: Destination  
 Period of Performance: 09/19/2010 to 12/31/2017

Add Item 6 as follows:

ASPR-17-01887- [\*\*\*]  
 Funds to cover CLN002  
 (Opt1) Indirect rate adjustment on existing contract with Achaogen  
 Contract Number  
 HHS0100201000046C  
 Obligated Amount: [\*\*\*]

Confidential Portions of this Exhibit marked as [\*\*\*] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

**FIRST AMENDMENT TO LEASE**  
**One Tower Place**

THIS FIRST AMENDMENT TO LEASE (" **First Amendment** ") is made and entered into as of the 7th day of April, 2017, by and between AP3-SF2 CT SOUTH, LLC, a Delaware limited liability company (" **Landlord** ") and ACHAOPEN, INC., a Delaware corporation (" **Tenant** ").

**RECITALS:**

- A. Landlord and Tenant entered into that certain Lease dated as of August 12, 2016 (the "Lease"), whereby Landlord leases to Tenant and Tenant leases from Landlord, certain space in the building (the "Building") located at One Tower Place, South San Francisco, California 94080. Landlord and Tenant also executed a commitment letter dated March 21, 2017 (the "Commitment Letter").
- B. By this First Amendment, Landlord and Tenant desire to memorialize Landlord's and Tenant's obligations in the Commitment Letter pertaining to the design and construction of a vertical exhaust system for the Building and to otherwise modify the Lease as provided herein. Landlord and Tenant acknowledge and agree that this First Amendment supersedes the Commitment Letter.
- C. Unless otherwise defined herein, capitalized terms as used herein shall have the same meanings as given thereto in the Lease.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

**AGREEMENT:**

- 1. **Vertical Exhaust System.** Landlord, at Landlord's sole cost and expense (and with no supervision/construction management fee to be charged by Landlord), shall construct a vertical exhaust system in the Building serving floors 3 through 8 (" **Vertical Exhaust** "), the design and construction of which Vertical Exhaust shall be pursuant to the following terms and conditions:
  - 1.1. **Design of Vertical Exhaust .** The Vertical Exhaust shall be designed by Landlord's architect after consultation with (and reasonable input from) Tenant. Tenant, in its sole discretion may elect to retain Craig DeBrine Associates (" **CRA** ") and Cermak Peterka and Petersen (" **CPP** ") as Tenant's consultants and, if Tenant elects to retain the same, Tenant shall be solely responsible for the costs incurred by Tenant in engaging CBA and/or CPP (or any other consultants). To the extent Tenant or Tenant's consultants review and approve the Preliminary Plans, the Final Working Drawings, or the Approved Working Drawings (all as defined below), Landlord acknowledges and agrees that Tenant and Tenant's consultants are doing so solely for the purpose of confirming that Tenant's operational needs are met, not as a designer or engineer for the purpose of identifying any errors, omissions or inconsistencies or for ensuring that the Preliminary Plans, Final Working Drawings, or

Approved Working Drawings satisfy any applicable laws, codes, or ordinances. Accordingly, Landlord agrees that Tenant shall not be responsible for any such errors, omissions or inconsistencies in the Preliminary Plans, Final Working Drawings, or Approved Working Drawings, nor shall it be responsible in the event such Preliminary Plans, Final Working Drawings, or Approved Working Drawings fail to satisfy any applicable laws, codes or ordinances.

- 1.2. Preliminary Plans. Within three (3) days of the full execution and delivery of this First Amendment by Landlord and Tenant, Tenant and Tenant's consultants shall meet with Landlord and Landlord's architect and provide Landlord and Landlord's architect with input (the "**Tenant's Input**") regarding the preliminary plans and specifications ("**Preliminary Plans**") for the Vertical Exhaust. Thereafter, Landlord shall cause Landlord's architect, based on Tenant's reasonable Input, to deliver Preliminary Plans to Tenant for Tenant's approval, not to be unreasonably withheld. Tenant shall approve or reasonably disapprove the Preliminary Plans thereto within five (5) business days after Landlord delivers the Preliminary Plan to Tenant or within three (3) business days after Landlord delivers any Preliminary Plan revisions to Tenant. This process shall be repeated until the Preliminary Plans are mutually approved by Landlord and Tenant. Failure of Tenant to respond to Landlord before the expiration of any such time periods set forth above shall be deemed Tenant's approval of the Preliminary Plans. Acting in good faith and reasonably, Landlord and Tenant shall mutually agree on the Preliminary Plans by no later than May 1, 2017 (or as soon thereafter as reasonably possible).
- 1.3. Final Working Drawings. Based on the approved Preliminary Plans, Landlord shall cause Landlord's architect and engineer to complete the architectural and engineering drawings for the Vertical Exhaust, and cause the architect to compile a fully coordinated set of architectural, structural and mechanical working drawings in a form which is complete to allow subcontractors to bid on the work and to obtain all applicable permits (collectively, the "**Final Working Drawings**") and shall submit the same to Tenant for Tenant's approval, not to be unreasonably withheld. The Final Working Drawings shall incorporate modifications to the Preliminary Plans as necessary to comply with the structural and system requirements of the Building as well as changes required by applicable laws. Except for changes required by applicable laws, any material Landlord modification to the Final Working Drawings shall be subject to Tenant's reasonable approval, not to be unreasonably withheld. Tenant shall approve or reasonably disapprove the Final Working Drawings within five (5) business days after Landlord delivers the same to Tenant or within three (3) business days after Landlord delivers any Final Working Drawing revisions thereto to Tenant; provided, however, that Tenant may only disapprove the Final Working Drawings to the extent the same are not in substantial conformance with the Preliminary Plans. Failure of Tenant to respond to Landlord before the expiration of any such time periods set forth above shall be deemed Tenant's approval of the Final Working Drawings. The Final Working Drawings, once approved (or deemed approved) by Tenant, may be referred to herein as the "**Approved Working Drawings**."
- 1.4. Approved Working Drawings. Landlord shall cause the architect to submit the Approved Working Drawings to the applicable local governmental agency for all applicable building permits necessary to allow the Contractor (as defined below), to commence and fully complete the construction of the Vertical Exhaust. Tenant agrees to provide Landlord with assistance to obtain any necessary permits so long as such assistance does not result in Tenant incurring out-of-pocket expenses (other than costs incurred by Tenant for the

services of CBA, CPP or any other consultants or third party costs). No material changes, modifications or alterations in the Approved Working Drawings may be made without the prior written consent of Landlord and Tenant, which consent shall not be unreasonably withheld.

- 1.5. **Contractor**. A contractor, under the supervision of and selection by Landlord, shall construct the Vertical Exhaust (the "**Contractor**"). The Vertical Exhaust shall be operational by December 31, 2017, subject to extension due to Force Majeure delays (as defined in Section 24.17 of the Lease); Tenant Delays (as defined below), governmental delays (including delays in Landlord obtaining a building permit) and other causes beyond Landlord's reasonable control. If such Vertical Exhaust is not operational by December 31, 2017 (as such date may be subject to extension as provided above), Tenant shall, during the period from January 1, 2018 and continuing until June 30, 2018 only (if the Vertical Exhaust is not operational during such period), be entitled to a Base Rent abatement equal to any actual, documented and reasonable fees ("**Tenant's Costs**") Tenant incurs in connection with having Tenant's laboratory work conducted by a third party and/or conducted in laboratory space other than the Building, but in no event shall such Base Rent abatement exceed Fifty Thousand Dollars (\$50,000.00) per month. The Base Rent abatement provided for any given month during the Lease Term shall be supported by paid invoices delivered by Tenant to Landlord evidencing (to Landlord's reasonable satisfaction) Tenant's Costs and Landlord's receipt of such paid invoices shall be a condition to Tenant receiving such Base Rent abatement. Such Base Rent abatement shall continue until the earlier of (i) the date the Vertical Exhaust is operational or (ii) June 30, 2018. Tenant agrees to use reasonable efforts to mitigate Tenant's Costs should the Vertical Exhaust not be operational by December 31, 2017 (as such date may be extended as provided above). In the event the Vertical Exhaust is not operational by June 30, 2018, subject to extension due to Force Majeure delays and Tenant Delays, then Tenant shall receive a twenty-five percent (25%) discount on its Base Rent starting from July 1, 2018 (as such date may be extended as provided above). For each additional month beyond July 31, 2018 for which the Vertical Exhaust is not operational, Tenant shall receive an additional seven and one-half percent (7.5%) discount on Base Rent from the prior month but in no event shall such Base Rent discount exceed seventy percent (70%) of the Base Rent payable by Tenant. For example, if the Vertical Exhaust system is not operational during the entire month of July, 2018, then Tenant will be entitled to a twenty-five percent (25%) Base Rent discount for such month. If the Vertical Exhaust system is not operational during the entire month of August, then Tenant will be entitled to a thirty-two and one-half percent (32.5%) Base Rent discount for such month. All such Base Rent discounts shall be prorated for partial months. Notwithstanding this discount, in no event shall Tenant owe less than 30% of Base Rent. Notwithstanding anything above to the contrary, the discounts shall only apply to the portion of the Premises occupied by Tenant and not any portion of the Premises occupied by any Transferee under Section 14.1 of the Lease or any special transferee pursuant to Section 14.8 of the Lease.
- 1.6. **Tenant Delays**. As used above, the "Tenant Delay(s)" shall mean any delays caused by any of the following:
  - 1.6.1. Tenant's failure to approve any matter requiring Tenant's approval within the mutually stipulated required time, subject to any agreed extensions, except to the extent such Tenant approval is deemed given in the absence of a timely response;
  - 1.6.2. Tenant's request for changes in the Preliminary Plans and/or the Approved

Working Drawings after the first date on which both Landlord and Tenant have approved the Preliminary Plans and/or the Final Working Drawings, except to the extent such changes are required by any applicable local agency as a condition of obtaining any necessary building or other permits or necessary to correct any errors or omissions made by Landlord's architect; and

- 1.6.3. any other acts or omissions of Tenant, or its agents, or employees if such acts or omissions are not cured within five (5) business days following Landlord's notice to Tenant;
- 1.7. Tenant's Representative. Tenant has designated Lee Swem as its sole representative with respect to the matters set forth in this First Amendment, who, until further notice to Landlord, shall have full authority and responsibility to act on behalf of the Tenant as required in this First Amendment.
- 1.8. Landlord's Representative. Landlord has designated Fritz Gutenberg as its sole representative with respect to the matters set forth in this First Amendment, who, until further notice to Tenant, shall have full authority and responsibility to act on behalf of the Landlord as required in this First Amendment.
- 1.9. Meetings. Both Landlord and Tenant shall use commercially reasonable, good faith, efforts and all due diligence to cooperate with each other to complete all phases of the design and construction of the Vertical Exhaust and, in that regard, shall meet on a scheduled bi- weekly basis to be determined by Landlord and Tenant, to discuss progress in connection with the same.
2. Tenant's Occupancy of the Premises. As part of the consideration for Landlord's execution of this First Amendment, Tenant agrees to occupy the office portion of the Premises (and so much of the lab portion as Tenant elects) no later than April 17, 2017 and to continue to occupy the same after such date, subject to the terms of the Lease and First Amendment.
3. Confirmation of Dates. Subject to the obligations in this First Amendment, the parties hereby confirm that (a) the Premises are Ready for Occupancy, and (b) the term of the Lease commenced as of March 23, 2017 for a term of ten (10) years and six (6) months ending on September 30, 2017 (unless sooner terminated as provided in the Lease). Tenant shall commence to pay rent as of March 23, 2017 (“**Rent Commencement Date**”).
4. Signing Authority. Each individual executing this First Amendment on behalf of Tenant and Landlord hereby represents and warrants that Tenant and Landlord, as the case may be, is a duly formed and existing entity qualified to do business in the State of California, that Tenant and Landlord have full right and authority to execute and deliver this First Amendment and that each person signing on behalf of Tenant and Landlord is authorized to do so.
5. No Further Modification. Except as set forth in this First Amendment, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect.

IN WITNESS WHEREOF, this First Amendment has been executed as of the day and year first above written.

"LANDLORD"

AP3-SF2 CT SOUTH, LLC,  
a Delaware limited liability company

By: /s/ Neil Fox

Name: Neil Fox

Its: ceo

"TENANT"

ACHAOGEN, INC., a Delaware corporation

By: /s/ Kenneth Hillan

Name: Kenneth Hillan

Its: CEO

4000 SHORELINE  
Achaogen, Inc. [Version 6]

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**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER  
PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)**

I, Kenneth J. Hillan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Achaogen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2017

/s/ Kenneth J. Hillan

Kenneth J. Hillan  
Chief Executive Officer  
(principal executive officer)

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER  
PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)**

I, Tobin C. Schilke, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Achaogen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2017

/s/ Tobin C. Schilke

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Tobin C. Schilke

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Chief Financial Officer

(principal financial and accounting officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Achaogen, Inc. (the “Company”) on Form 10-Q for the fiscal quarter ended June 30, 2017, as filed with the Securities and Exchange Commission (the “Report”), Kenneth J. Hillan, Chief Executive Officer of the Company, and Tobin C. Schilke, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2017

/s/ Kenneth J. Hillan

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Kenneth J. Hillan  
Chief Executive Officer  
(principal executive officer)

/s/ Tobin C. Schilke

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Tobin C. Schilke  
Chief Financial Officer  
(principal financial and accounting officer)