Achaogen Inc
Form 10-Q
May 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-36323

ACHAOGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	68-0533693
(State or other jurisdiction of incorporation or organization)	(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)

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		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company		

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 May 2, 2018, there were 44,796,291 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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)

	March 31, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 94,898	$ 145,219
Short-term investments	49,100	19,572
Contracts receivable	1,789	1,357
Prepaids and other current assets	8,944	6,367
Restricted cash	6,998	5,891
Total current assets	161,729	178,406
Property and equipment, net	17,228	14,810
Restricted cash	1,320	3,855
Other long-term assets	2,828	—
Total assets	$ 183,105	$ 197,071
Liabilities, contingently redeemable common stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,870	$ 6,862
Accrued liabilities	14,657	15,441
Loan payable, current portion	—	12,500
Deferred revenue	1,545	2,100
Total current liabilities	23,072	36,903
Loan payable, long-term	24,472	9,457
Warrant liability	12,161	9,774
Derivative liability	830	686
Deferred rent	9,477	8,289
Total liabilities	70,012	65,109
Commitments and contingencies (Note 10)		
Contingently redeemable common stock (Note 9)	10,000	10,000
Stockholders' equity		
Common stock, $0.001 par value, 290,000,000 shares authorized at March 31, 2018 and December 31, 2017; 44,791,564 and 42,515,015 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	45	42
Preferred stock, $0.001 par value, 10,000,000 shares authorized and zero shares issued and outstanding at March 31, 2018 and December 31, 2017	—	—

Additional paid-in-capital	523,141	494,758
Accumulated deficit	(420,067)	(372,838)
Accumulated other comprehensive loss	(26)	—
Total stockholders' equity	103,093	121,962
Total liabilities, contingently redeemable common stock and stockholders' equity	$ 183,105	$ 197,071

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 March 31,	
	2018	2017
Contract revenue	$2,143	$7,463
Operating expenses		
Research and development	30,911	18,597
General and administrative	15,069	6,751
Total operating expenses	45,980	25,348
Loss from operations	(43,837)	(17,885)
Interest expense	(604)	(706)
Change in warrant and derivative liabilities	(2,531)	(14,956)
Loss on debt extinguishment	(819)	-
Other income, net	562	288
Net loss	$(47,229)	$(33,259)
Basic and diluted net loss per common share	$(1.06)	$(0.93)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	44,356,570	35,725,876

See accompanying notes to condensed consolidated financial statements.

Achaogen, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2018	2017
Net loss	$(47,229)	$(33,259)
Other comprehensive (loss) income:		
Net unrealized gain (loss) on available-for-sale securities	(26)	(52)
Total comprehensive loss	$(47,255)	$(33,311)

See accompanying notes to condensed consolidated financial statements.

Achaogen, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(47,229)	$(33,259)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	561	113
Amortization of (discount) premium on short-term investments	(97)	(42)
Stock-based compensation expense	4,245	2,911
Change in warrant and derivative liabilities	2,531	14,956
Loss on debt extinguishment	819	—
Non-cash interest expense relating to notes payable	97	207
Change in operating assets and liabilities:		
Contracts receivable	(432)	6,285
Prepaids and other assets	(2,577)	(6,810)
Other long-term assets	(2,828)	—
Accounts payable and accrued liabilities	(2,434)	2,316
Deferred revenue	(555)	—
Other liabilities	1,188	(95)
Net cash used in operating activities	(46,712)	(13,418)
Cash flows from investing activities:		
Purchase of property and equipment	(1,321)	(1,185)
Purchase of short-term investments	(49,057)	(86,759)
Maturities of short-term investments	19,600	19,256
Net cash used in investing activities	(30,778)	(68,688)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	24,002	—
Payments of issuance costs, related to underwritten public offering	—	(42)
Proceeds from the issuance of common stock in connection with equity incentive plans	139	535
Proceeds from exercise of stock warrants	—	288
Proceeds from loan payable, net of issuance costs	24,432	—
Repayment of loan payable	(22,833)	—
Net cash provided by financing activities	25,740	781
Net increase in cash, cash equivalents, and restricted cash	(51,749)	(81,325)
Cash, cash equivalents, and restricted cash at beginning of period	154,965	119,341
Cash, cash equivalents, and restricted cash at end of period	$103,216	$38,016
Supplemental disclosures of cash flow information		
Interest paid	$507	$499
Supplemental disclosures of noncash investing and financing information		

Reclassification of warrant liability to additional paid-in capital	$—	$1,521
Purchases of property plant and equipment included in deferred rent	$—	$3,794
Purchases of property plant and equipment included in accounts payable and accrued expenses	$1,658	$—

See accompanying notes to condensed consolidated financial statements.

Achaogen, Inc.

March 31, 2018

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 innovative antibacterial treatments against multi-drug resistant ("MDR") gram-negative infections.

The Company is developing plazomicin, its lead product candidate, for the treatment of bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae ("CRE"). On January 2, 2018, the Company announced the acceptance of a New Drug Application ("NDA") for substantive review by the U.S. Food and Drug Administration ("FDA) for plazomicin, seeking approval to treat complicated urinary tract infections ("cUTI"), including acute pyelonephritis ("AP") and bloodstream infections ("BSI") due to certain Enterobacteriaceae in patients who have limited or no alternative treatment options.

The NDA is supported by data from two Phase 3 clinical trials, EPIC (Evaluating Plazomicin In cUTI) and CARE (Combating Antibiotic Resistant Enterobacteriaceae), which evaluated the safety and efficacy of plazomicin in patients with serious infections caused by gram-negative pathogens, including ESBL producing Enterobacteriaceae and CRE. The EPIC study was a Phase 3 trial of plazomicin for the treatment of patients with cUTI and acute pyelonephritis ("AP"). The CARE study was a Phase 3 resistant pathogen trial designed to evaluate the efficacy and safety of plazomicin in patients with serious bacterial infections due to CRE.

The Company is also developing an orally-available antibacterial candidate, C-Scape, a combination of ceftibuten, an approved third generation cephalosporin, and clavulanate, an approved -lactamase inhibitor to address a serious unmet need for an effective oral treatment for patients with cUTI, including AP, caused by ESBL-producing Enterobacteriaceae. On January 2, 2018, the Company announced positive Phase 1 top-line results and continues to do additional development on C-Scape including a Phase 1 Clinical Pharmacology study.

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 and preparing for their commercialization, 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 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 period ended March 31, 2018 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, 2017 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, 2017 included in the Company's Annual Report on Form 10-K.

Liquidity and Going Concern

On April 7, 2015, the Company entered into a Common Stock Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company 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 at-the-market ("ATM") equity offering program under which Cowen acts as sales agent. During the three-month period ended March 31, 2018, the Company sold 2,144,454 shares of common stock under the Sales Agreement, at a weighted-average price of approximately $11.51 per share for aggregate gross proceeds of $24.7 million and aggregate net proceeds of $24.0 million. As of March 31, 2018, the Company had sold 3,250,003 shares of common stock under the Sales Agreement for aggregate gross proceeds of $30.0 million and aggregate net proceeds of $29.2 million. No shares remain available for sale under the Sales Agreement.

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.

In September 2017, the Company was awarded a contract (the "C-Scape Contract") valued at up to $18.0 million in grant funding from the Biomedical Advanced Research and Development Authority ("BARDA") to support the development of C-Scape. The C-Scape Contract includes a base period with committed funding of $12.0 million and subsequent option periods that, if exercised, would bring the total value of the award to $18.0 million.

On February 26, 2018, the Company entered into a new loan and security agreement with Silicon Valley Bank, pursuant to which Silicon Valley Bank agreed to make available to the Company term loans with an aggregate principal amount of up to $50.0 million, $20.9 million of which was used to repay our loan with Solar Capital Ltd., $4.1 million of which was provided to us on February 26, 2018 and $25.0 million of which remains available for borrowing.

On February 27, 2018, the Company filed an amended Registration Statement on Form S-3 (the "2018 Shelf Registration Statement") covering the offering of up to $250.0 million of common stock, preferred stock, debt securities, warrants and units. In addition, on February 27, 2018, the Company filed a prospectus supplement to the 2018 Shelf Registration Statement covering the offering, issuance and sale of up to $50.0 million shares of the Company's common stock in ATM offerings pursuant to a Common Stock Sales Agreement entered into with Cowen and Company, LLC (the "2018 Sales Agreement").

The Company has incurred losses and negative cash flows from operations every year since its inception. As of March 31, 2018, the Company had unrestricted cash, cash equivalents and short-term investments of approximately $144.0 million and an accumulated deficit of approximately $420.1 million. The Company believes that its existing

cash, cash equivalents and short-term investments, together with the additional $25.0 million term loan available under our loan and security agreement with Silicon Valley Bank, will be sufficient to fund its current planned operations for at least the next twelve months from the filing of this report. The Company plans to raise additional funds through equity or debt financing, government contracts, third party collaborations or other sources to permit additional investments in the commercialization of plazomicin and continued research and development efforts. These funding sources may not be available at terms acceptable to the Company or at all. If the Company is unable to raise additional funding, a reduction in the scope of its research and development programs and other operations may become necessary.

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 derivative and warrant 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 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 March 31, 2018 and December 31, 2017, cash and cash equivalents consisted of bank deposits, cash, commercial paper, money market funds, cash repurchase agreement investments and overnight cash sweep investments in government 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 (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 March 31, 2018 and December 31, 2017, the Company had restricted cash of $8.3 million and $9.7 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):

	March 31, 2018	December 31, 2017
Cash and cash equivalents	$94,898	$ 145,219
Restricted cash, current	6,998	5,891
Restricted cash, non-current	1,320	3,855
Total cash, cash equivalents, and restricted cash	$103,216	$ 154,965

In May 2017, the Company received $13.2 million of funding from the Gates Foundation from the Grant Funds and Gates Investment (see Note 1). The Letter Agreement restricts the Company's use to expenditures that are reasonably attributable to the activities required to support the research projects funded by the Gates Foundation, including an allocation of overhead and administrative expenses. As of March 31, 2018 and December 31, 2017, the Company had $7.8 million and $9.2 million, respectively, of restricted cash related to the cash provided by the Gates Foundation. As of March 31, 2018 and December 31, 2017, the Company had $0.5 million of restricted cash, which relates to the Company's facility leases.

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 regarding resource allocation and assessing performance. The Company has one operating segment.

Customer Concentration

For the three-month periods ended March 31, 2018 and 2017, the Company's revenue was generated from funding pursuant to U.S. government contracts and a non-profit foundation grant. All contracts receivable relate to funding from U.S. government contracts.

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, overnight sweep 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 March 31, 2018 and December 31, 2017, the Company had not experienced any credit losses in such accounts or investments.

Revenue Recognition

The Company evaluated Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (ASC 606) and determined that the government contracts and non-profit foundation grant are not in scope as the government entities and foundations are not customres under the agreements. For services performed under these contracts and grant agreements, 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. Government contracts provide the Company with payments for certain types of expenditures in return for research and development activities over a contractually defined period. Revenue from government 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 statements of operations.

Funds received from third parties under contract or grant arrangements are recorded as revenue if the Company is deemed to be the principal participant in the arrangements because the activities under the contracts or grants are part of the Company's development programs. If the Company is not the principal participant, the funds from contracts or grants 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 there is reasonable assurance that the funds will be received. Funds received in advance are recorded as deferred revenue. Management has determined that the Company is the principal participant under the Company's government contract arrangements and non-profit grant agreement, and accordingly, the Company records amounts earned under these arrangements as 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, non-profit grants and government contracts. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and recognized as an expense as the goods are delivered or the related services are performed.

For certain research and development services where the Company has not yet been invoiced or otherwise notified of actual cost from the third-party contracted service providers, the Company is required to estimate the extent of the services that have been performed on the Company's behalf and the associated costs incurred at each reporting period. The majority of the service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of the accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to the Company at that time. The Company periodically confirms the accuracy of the estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued research and development expenses include services from:

- contract research organizations ("CROs") and other service providers in connection with clinical studies;
- contract manufacturers in connection with the production of clinical trial materials; and
- vendors in connection with preclinical development activities.

The Company bases the expenses related to preclinical studies and clinical trials on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage such studies and trials on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which these services will be performed and the level of effort to be expended and costs to be incurred during each reporting period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts the accrual accordingly. The Company's estimation of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting changes in estimates in any particular period. To date, there have been no material adjustments from the Company's estimates to the amount actually incurred.

Property and Equipment, Net

Property and equipment consist of office equipment, laboratory equipment, and leasehold improvements and are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years. Leasehold improvements are amortized over their estimated useful lives or the remaining lease term, whichever is shorter. Maintenance and repair costs are recorded as a component of operating expenses in the Company's consolidated statement of operations when incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The

impairment charge is determined based upon the excess of the carrying value of the asset over its estimated fair value, with estimated fair value determined based upon an estimate of discounted future cash flows or other appropriate measures of estimated fair value. As of March 31, 2018 and December 31, 2017, the Company did not have any impairment charges.

Warrant Liability

On June 3, 2016, the Company issued warrants to purchase 1,999,999 shares of its common stock pursuant to a Securities Purchase Agreement (the “Purchase Agreement”) in connection with a private placement financing transaction (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. As of March 31, 2018, a warrant to purchase 1,178,782 shares of the Company's common stock remains outstanding and unexercised.

Contingently Redeemable Common Stock

In May 2017, 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 (see Note 1). Common stock with embedded redemption features that are settled at the option of the holder, are considered redeemable common stock. Redeemable common stock is considered to be temporary equity and presented in a section between liabilities and equity on the Company's consolidated balance sheets. Subsequent adjustment of the amount presented in temporary equity is required only if the Company determines that it is probable that the instrument will become redeemable. Upon termination of the redemption features, the redeemable common stock is reclassified into equity. As of March 31, 2018, 407,331 shares of contingently redeemable common stock remain as temporary equity.

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 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. The Company adopted this standard on January 1, 2018 noting it did not have a material impact on the Company's financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments- Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilties, which includes provisions to accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. The amended guidance requires equity securities, except for those accounted for under the equity method of accounting, with determinable fair values to be measured at fair with changes in fair value recognized in net income (loss). This ASU will be effective for the Company for annual reporting periods, including interim reporting periods, beginning after December 15, 2017. The Company adopted this standard on January 1, 2018 noting it did not have a material impact on the Company's financial statements.

In March 2018, the FASB issued ASU No. 2018-05, Income Taxes (Topic 740), Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118. The amendments add various Securities and Exchange Commission ("SEC) paragraphs pursuant to the issuance of SEC Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("Act") ("SAB 118"). The SEC issued SAB 118 to address concerns about reporting entities' ability to timely comply with the accounting requirements to recognize all of the effects of the Act in the period of enactment. SAB 118 allows disclosure that timely determination of some or all of the income tax effects from the Act are incomplete by the due date of the financial statements and if possible to provide a reasonable estimate. The Company has provided a reasonable estimate in the notes to the 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.

For the three-month periods ended March 31, 2018 and 2017, 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 March 31, 2018 and 2017:

	Three Months Ended March 31,	
	2018	2017
Shares subject to options to purchase common stock	6,032,808	4,470,187
Restricted stock units	1,201,246	800,658
Shares subject to warrants to purchase common stock	1,196,296	1,231,659

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, restricted cash, 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, including cash held at overnight sweep accounts. 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 the loan repaid in February 2018 and a warrant liability in connection with the Private Placement.

As of March 31, 2018 and December 31, 2017, 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):

	March 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets				
Level 1:				
Restricted cash	8,318	—	—	8,318
Money market funds	37,445	—	—	37,445
U.S. Treasury bills	19,889	—	(5)	19,884
Subtotal	65,652	—	(5)	65,647
Level 2:				—
Commercial paper	42,365	—	—	42,365
Corporate securities	19,325	—	(21)	19,304
Other debt securities	25,000	—	—	25,000
Subtotal	86,690	—	(21)	86,669
Total	$152,342	$ —	$ (26)	$152,316
Reported as:				
Cash and cash equivalents				$94,898
Short-term investments				$49,100
Restricted cash				$8,318
Liabilities, Level 3				
Warrant Liability				$12,161
Derivative Liability				$830
Total				$12,991

	December 31, 2017			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets				
Level 1:				
Restricted cash	9,746	—	—	9,746
Money market funds	58,769	—	—	58,769
U.S. Treasury bills	4,992	—	—	4,992
Subtotal	73,507	—	—	73,507
Level 2:				
Commercial paper	46,040	—	—	46,040
U.S. agency securities	4,990	—	—	4,990
Other debt securities	50,000	—	—	50,000
Subtotal	101,030	—	—	101,030
Total	$174,537	$ —	$ —	$174,537
Reported as:				
Cash and cash equivalents				$145,219

Short-term investments	$ 19,572
Restricted cash	$ 9,746
Liabilities, Level 3	
Warrant Liability	$ 9,774
Derivative Liability	$ 686
Total	$ 10,460

The amortized cost and estimated fair value of the debt securities by contractual maturity are summarized as follows:

	As of March 31, 2018		As of December 31, 2017	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Due in one year or less	$144,025	$143,999	$164,791	$164,791
Due after one year through five years	-	-	-	-
Total debt securities	$144,025	$143,999	$164,791	$164,791

All available-for-sale securities held as of March 31, 2018 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 $39.2 million as of March 31, 2018. 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 period ended March 31, 2018.

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 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 estimated fair value of the Success Fee is recorded as a derivative liability and included in other long-term liabilities on the accompanying consolidated balance sheet. As of March 31, 2018 the derivative liability increased by $0.1 million to $0.8 million from December 31, 2017, primarily as a result of a change in the estimated cost of debt and the time value of money, which is presented as a component of change in warrant and derivative liabilities in the Company’s condensed consolidated statements of operations.

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. as a result of FDA approval to market plazomicin, and ii) a discount rate of 5.8% which was derived from the Company's estimated cost of debt, updated to reflect the new loan and security agreement with Silicon Valley Bank. The estimated fair value of the derivative liability is most sensitive to a change in the discount rate. If the discount rate decreased by 5%, the fair value of the derivative liability as of March 31, 2018 would change by approximately $0.1 million. For the three-month period ended March 31, 2018, there were no material changes to the key assumptions used in the calculation of the estimated fair value other than the decrease in the discount rate from 13% to 5.8%. 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 per share. 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 June 3, 2016, the closing date of the Private Placement, 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 March 31, 2018 and December 31, 2017, the estimated fair values of the outstanding warrants were approximately $12.2 million and $9.8 million, respectively. The change in the estimated fair value is primarily due to the change 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.

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 March 31, 2018 and December 31, 2017, the estimated fair values of the warrants were determined using Black-Scholes with the following assumptions:

	March 31, 2018	December 31, 2017
Expected volatility	80%	80%
Expected term	3.2 years	3.4 - 4.3 years
Risk-free interest rate	2.4%	1.6 - 2.0%
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 March 31, 2018 would change by approximately $0.7 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 three-month period ended March 31, 2018 (in thousands):

	Estimated Fair Value of Warrant Liability	Estimated Fair Value of Derivative Liability
Balance of Level 3 Liabilities at December 31, 2017	$ 9,774	$ 686
Change in estimated fair value of warrant liability	2,387	—
Change in estimated fair value of derivative liability	—	144
Balance of Level 3 Liabilities at March 31, 2018	$ 12,161	$ 830

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4. Balance Sheet Components

Prepaids and other current assets

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

	March 31, 2018	December 31, 2017
Deferred manufacturing costs	$ 6,041	$ 4,317
Prepaid expenses	2,152	1,755
Other current assets	751	295
	$ 8,944	$ 6,367

Property and Equipment, net

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

	March 31, 2018	December 31, 2017
Office equipment	$ 1,658	$ 863
Laboratory equipment	7,184	6,663
Leasehold improvements	9,526	9,355
Construction-in-progress	2,532	1,040
	20,900	17,921
Less: accumulated depreciation	(3,672)	(3,111)
Property and equipment, net	$ 17,228	$ 14,810

Depreciation and amortization expense for the three-month periods ended March 31, 2018 and 2017 was $0.6 million and $0.1 million, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2018	December 31, 2017
Accrued clinical and development expenses	$ 5,229	$ 6,480
Payroll and related bonus expenses	4,656	6,281
Other	4,772	2,680
	$ 14,657	$ 15,441

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 healthcare 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 approximately $6.8 million. 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.

As of March 31, 2018, the Company has incurred $3.8 million in milestone payments and these costs were fully recorded as research and development expense. The Company recorded $0.1 million and $0.2 million of research and development expense during the three-month periods ended March 31, 2018 and 2017, respectively.

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 approximately $20.6 million. 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. In 2017, Ligand Pharmaceuticals Incorporated ("Ligand") acquired Crystal and the platform became a part of the OmniAb platform. This acquisition does not materially impact the Company's ongoing collaboration.

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 March 31, 2018, 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 March 31, 2018, the Company had no outstanding payments due under the license.

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. As of March 31, 2018, the Company has recorded revenue of $1.6 million under this agreement.

The Company recorded contract revenue of $0.6 million and zero, respectively under this agreement during the three-month periods ended March 31, 2018 and 2017.

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 diseases caused by antibiotic-resistant pathogens and biothreats. The original contract included committed funding of $27.6 million for the first two years of the contract and subsequent options exercisable by BARDA to provide additional funding. As of March 31, 2018, the original contract and the three-exercised options and modifications total $124.4 million of obligated funding, of which a total of $124.3 million has been recorded as revenue, with $0.1 million remaining available from the committed funding under this BARDA contract.

In September 2017, the Company was awarded the C-Scape Contract (the "C-Scape Contract") valued at up to $18.0 million from BARDA to support the development of C-Scape. The C-Scape Contract includes a base period with committed funding of $12.0 million and subsequent option periods that, if exercised, would bring the total value of the award to $18.0 million. As of March 31, 2018, the Company has recorded revenue of $2.4 million, with $9.6 million remaining available from the committed funding under the C-Scape Contract.

The Company recorded contract revenue of $1.5 million and $7.1 million under these agreements during the three-month periods ended March 31, 2018 and 2017, respectively.

7. Borrowings

Solar Capital Ltd. Loan Agreement

On August 5, 2015, the Company entered into a loan and security agreement (the "Solar Loan Agreement") with Solar Capital Ltd. (the "Solar Capital") pursuant to which Solar Capital 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 bore interest per annum at 6.99% plus the greater of 1% or the one-month LIBOR. The obligation also included a final fee of $2.0 million, representing 8% of the term loan currently funded, which accreted over the life of the loan as interest expense. On February 26, 2018, the Company terminated the Solar Loan Agreement and repaid the outstanding principal and accrued interest expense of $20.9 million. For the three-month period ended March 31, 2018, the Company recorded a loss from debt extinguishment of $0.8 million as the difference between the net carrying amount of the Solar Capital debt and the amount paid.

On August 5, 2015, pursuant to the Solar Loan Agreement, the Company entered into a Success Fee Agreement with Solar Capital under which the Company agreed to pay Solar Capital $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 estimated fair value of the Success Fee is recorded as a derivative liability and included in other long-term liabilities on the accompanying consolidated balance sheet.

Silicon Valley Bank Loan Agreement

On February 26, 2018, the Company entered into a loan and security agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB"). The Loan Agreement provides for (i) a $25.0 million Term A loan facility with a maturity of five years (the "Term A Loan") and (ii) an up to $25.0 million Term B loan facility, which may be drawn, subject to certain conditions, by the Company during the first 12 months after February 26, 2018 (the "Term B Loans" and collectively, with the Term A Loan, the "Term Loans"). Each Term B Loan has a maturity of four years. As of March 31, 2018, the Company received initial funding from the Term A Loan of $25.0 million, which was primarily used to repay the Company's prior loan agreement with Solar Capital.

Borrowings under the Term A Loan bear interest at a floating per annum rate equal to the greater of (a) the prime rate minus 1.50% and (b) 3.00%, and the Term B Loans bear interest through maturity at a floating per annum rate equal to the greater of (a) 1.00% above the prime rate and (b) 5.50%. In addition to paying interest on outstanding principal, the Company will be required to

pay an unused Term B Loan fee of 1.00% of the commitments under the Term B Loans if the Company does not borrow any Term B Loans.

The Company is permitted to make interest-only payments on the Term A Loan through February 2020 and the Term B Loans for the first twenty-four (24) months following the funding date of each respective Term B Loan after which the Company will be required to repay the Term A Loan in 36 consecutive equal monthly installments of principal and repay any Term B Loans in 24 consecutive equal monthly installments of principal. The Company is obligated to pay a fee equal to 6.00% of the funded Term Loans upon the earliest to occur of the maturity date, the prepayment or repayment of such Term Loans or the termination of the Loan Agreement. The final payment fee of $1.5 million, which represents 6% of the funded Term A Loan is accreted under the effective interest method over the life of the loan as interest expense. The Company may voluntarily prepay all, but not less than all, of the outstanding Term Loans. The Term Loans are secured by substantially all of the Company's assets, except for its intellectual property which is subject to a negative pledge and certain other customary exclusions. The Loan Agreement contains customary representations, warranties and covenants. The Company is required to have cash on deposit at Silicon Valley Bank equal to the greater of (a) $48.0 million and (b) the "Monthly Cash Burn," which is defined as the difference of (1)(i) net loss plus (ii) unfinanced capital expenditures minus (2)(i) depreciation and amortization expenses, (ii) non-cash stock compensation expense and (iii) other non-cash expenses as approved by SVB. If at any time the Company's aggregate balances at SVB are less than the foregoing, the Company is required to deposit at SVB cash collateral in an amount equal to the outstanding Term A Loan. As of March 31, 2018, the Company had maintained the compensating balance of $48.0 million, which was included in cash and cash equivalents on the consolidated balance sheet.

Pursuant to the SVB Loan Agreement, the Company incurred $1.2 million of debt issuance costs related to external legal and transaction fees. The Company recorded $0.6 million of debt issuance costs as a direct deduction from the carrying value of the Term A Loan which are amortized as interest expense using the effective-interest method over the term of the Term A Loan. The remaining $0.6 million of debt issuance costs related to the unfunded Term B Loan is recorded in Prepaids and Other Current Assets on the consolidated balance sheet and is amortized on a straight-line basis over the draw period of the Term B Loan.

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

	March 31, 2018
2018	$ —
2019	—
2020	6,944
2021	8,333
2022	8,333
Thereafter [1]	2,889
Total principal and final fee payments	26,500
Unamortized debt issuance costs and final fee	(2,028)
Loan payable, long-term	$ 24,472

(1) Includes $1.5 million final fee payment

The Company recorded interest expense related to the loans of $0.6 million and $0.7 million for the three-month periods ended March 31, 2018 and 2017, respectively.

8. Stockholders' Equity

Stockholders' Equity

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 ATM equity offering. The Company entered into a Common Stock 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.

During the three-month period ended March 31, 2018, the Company sold 2,144,454 shares of common stock under the Sales Agreement, at a weighted-average price of approximately $11.51 per share for aggregate gross proceeds of $24.7 million and aggregate net proceeds of $24.0 million. As of March 31, 2018, the Company had sold 3,250,003 shares of common stock under the Sales Agreement for aggregate gross proceeds of $30.0 million and aggregate net proceeds of $29.2 million. No shares remain available for sale under the Sales Agreement.

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 February 27, 2018, the Company filed an amended Registration Statement on Form S-3 (the "2018 Shelf Registration Statement") covering the offering of up to $250.0 million of common stock, preferred stock, debt securities, warrants and units. In addition, on February 27, 2018, the Company filed a prospectus supplement to the 2018 Shelf Registration Statement covering the offering, issuance and sale of up to $50.0 million shares of its common stock in ATM offerings pursuant to a Common Stock Sales Agreement (the "2018 Sales Agreement") entered into with Cowen and Company, LLC on February 27, 2018. As of March 31, 2018 $50.0 million of common stock remained available to be sold under the 2018 Sales Agreement, subject to certain conditions specified therein.

Warrants

During 2012 and 2011, the Company issued warrants to Oxford Finance LLC and SVB to purchase 20,016 and 10,008 shares, respectively, of its Series C convertible preferred stock at an exercise price of $11.99 per share. The warrants were issued in connection with a loan and security agreement, which was repaid in full in June 2014. Immediately prior to the closing of the Company's initial public offering, these warrants automatically converted into warrants exercisable for shares of common stock, resulting in the reclassification of the related preferred stock warrant liabilities to additional paid-in capital.

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 per share 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.

As of March 31, 2018 the following warrants to purchase shares of common stock were outstanding and exercisable:

Warrant Holder	Issue Date	In Connection With	Warrant to Purchase	Shares	Exercise Price	Expiration Date
Oxford Finance LLC	4/30/2012	Loan agreement	Common stock	11,676	$ 11.99	11/1/2021
Oxford Finance LLC	11/1/2011	Loan agreement	Common stock	5,838	$ 11.99	11/1/2021
Growth Equity Opportunities Fund IV, LLC	6/3/2016	Private Placement	Common stock	1,178,782	$ 3.66	6/3/2021
				1,196,296		

Warrants outstanding as of March 31, 2018 and December 31, 2017 have a weighted-average exercise price of $3.78

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, 2018, the compensation committee of the board of directors approved an evergreen increase of 1,700,600 shares that may be granted in accordance with the terms of the 2014 Plan. As of March 31, 2018, 1,011,679 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 March 31, 2018, a total of 2,050,000 shares of common stock have been authorized under the Inducement Plan. As of March 31, 2018, 19,680 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, 2018, the compensation committee of the board of directors approved an evergreen increase of 318,863 shares that may be granted in accordance with the terms of the ESPP. As of March 31, 2018, 411,716 shares of common stock have been issued to employees participating in the ESPP and 593,814 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 March 31, 2018 and December 31, 2017 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 March 31, 2018, a total of 825,543 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 and related information:

	Shares Subject to Options Outstanding	Weighted-Average Exercise Price
Balance, December 31, 2017	4,838,598	$ 11.63
Options granted	1,350,091	$ 10.68
Options exercised	(19,616)	$ 7.07
Options cancelled	(136,265)	$ 12.28

Balance, March 31, 2018	6,032,808	$ 11.42

The following table summarizes RSU activity under the stock plans and related information:

	RSU Awards Outstanding	
	Number of Shares	Weighted-Average Grant Date Fair Market Value
Balance, December 31, 2017	891,232	$ 14.34
RSUs granted	473,883	$ 10.69
RSUs released	(112,479)	$ 16.95
RSUs cancelled	(51,390)	$ 12.07
Balance, March 31, 2018	1,201,246	$ 12.76

Stock-based compensation expense recognized for the three-month periods ended March 31, 2018 and 2017 in the Company’s condensed consolidated statements of operations was as follows (in thousands):

	Three Months Ended March 31,	
	2018	2017
Research and development	$2,258	$1,602
General and administrative	1,976	1,090
Total	$4,234	$2,692

Stock-based compensation expense for the three-month period ended March 31, 2017 includes $0.7 million of expense that relates to the stock options and restricted stock units held by the former Chief Medical Officer, which were modified upon his resignation in March 2017.

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 and Contingencies

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 obligated the Company to make upfront and nonrefundable advance payments which have been capitalized as prepaid and other current assets and other long-term 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 and other long-term 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. As of March 31, 2018 and December 31, 2017, the Company has recorded approximately $7.3 million and $4.3 million, respectively as prepaid and other current assets and other long-term assets and, during the three-month periods ended March 31, 2018 and 2017, has recognized $0.3 million and $0.9 million, respectively, as research and development expenses, related to the Work Plans. 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 March 31, 2018, $10.8 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 $28.2 million.

Facilities Lease Obligation

In August 2016, the Company entered into a non-cancelable agreement (the "Lease") to lease 47,118 square feet of office, laboratory and research and development space (the “Original Space”) for the Company's new principal executive offices in South San Francisco. In July 2017, the Company entered into an amendment (the “Lease Amendment”) to lease an additional 51,866 square feet of space (the “Expansion Space”) for a total of 98,984 square feet (the “Premises”). The Lease commenced in March 2017, after the substantial completion of certain improvements ("Tenant Improvements") required under the Lease and the Company moved into the Original Space in April 2017. The lease for 18,888 square feet of the Expansion Space commenced in August 2017 and the remainder 32,978 square feet commenced in January 2018. The lease term for the Premises is through January 31, 2028 (the “Lease Term”) and contains an option to extend the Lease Term for an additional 5 years. Base rent for the first year for the Original Space is approximately $2.9 million. The base rent increases approximately 3.5% in each subsequent year of the Lease Term. The Lease also provides for rent abatement of approximately $1.8 million and $2.0 million for the first year of the Lease Term for the Original Space and Expansion Space, respectively.

The Company has a one-time improvement allowance of $5.7 million for the Tenant Improvements (the "Original Allowance"). The Landlord disbursed the Original Allowance for the Tenant Improvements on behalf of the Company. At its election, the Company is also entitled to an additional improvements allowance of $0.9 million ("Original Additional Allowance"). Effective August 17, 2017, the Company elected to use the Original Additional Allowance and the base rent was increased by an aggregate of $1.7 million over the Lease Term. As of March 31, 2018, the Company has recorded approximately $6.6 million within leasehold improvements under property, plant and equipment, net in the condensed consolidated balance sheet related to costs incurred under the Original Allowance and the Original Additional Allowance. The Lease Amendment provides for a one-time improvement allowance of $1.0 million for certain tenant improvements and, at its election, the Company is also entitled to an additional improvements allowance of $1.5 million (“Expansion Additional Allowance”). In the event the Company elects to use the Expansion Additional Allowance, the base rent will be increased as calculated in the Lease Amendment. Pursuant to the Lease Amendment, the Company holds the option to pay the balance of the Original Additional Allowance and Expansion Additional Allowance in full any time within the first 36 months of the Lease Term.

Future minimum lease payments under the operating leases as of March 31, 2018 are as follows (in thousands):

Year Ending December 31,	Amounts
2018	$ 3,713
2019	6,201
2020	6,418
2021	6,645
2022	6,877
Thereafter	38,780

Total minimum lease payments	$ 68,634

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Rent expense was $1.5 million and $0.2 million for the three-month periods ended March 31, 2018 and 2017, respectively.

Guarantees and Indemnifications

As permitted under Delaware law and in accordance with the Company's bylaws, the Company is required to indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its directors and officers. The Company believes the fair value of the indemnification rights and agreements is minimal. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of March 31, 2018 and December 31, 2017.

11. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Based upon the Company's history of operating losses and the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company’s otherwise recognizable net deferred tax assets. There was no significant income tax provision or benefit for the three months ended March 31, 2018 or 2017.

On December 22, 2017, the Tax Cuts and Jobs Act (the “Act”) was enacted into law in the United States. The Act reduces the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. As of March 31, 2018, the Company has not completed the accounting for the tax effects as a result of the Act. However, the Company has made a reasonable estimate of the effects on its existing deferred tax balances and recognized a provisional amount of $40.9 million as of December 31, 2017. In some cases, the Company has not been able to make a reasonable estimate and continues to account for those items based on our existing accounting under ASC 740, Income Taxes, and the provisions of the tax laws that were in effect immediately prior to the Act. In all cases, the Company will continue to make and refine its calculations as additional analysis and more thorough understanding of the tax law is completed.

Pursuant to SAB 118 (regarding the application of ASC 740 associated with the enactment of the Act), the Company remeasured certain tax assets and liabilities based on the rates the Company expects them to reverse in the future, which is generally 21%. The Company is still analyzing certain aspects of the Act and refining its calculations, which could potentially affect the measurement of these balances or give rise to new deferred tax amounts. The provisional amount recorded related to the remeasurement of the deferred tax balance was $40.9 million as of December 31, 2017, which was fully offset by a valuation allowance.

12. Subsequent Event

On April 26, 2018, the Company entered into an agreement with CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator), under which the Company was awarded $2.4 million, with a possibility of up to $9.6 million in additional funding based on achievement of certain project milestones. The funding was awarded to support the development of a next-generation broad-spectrum aminoglycoside antibiotic capable of overcoming clinically-relevant resistance mechanisms and potentially treating highly-resistant gram-negative pathogens such as the Enterobacteriaceae family, Acinetobacter baumannii, and Pseudomonas aeruginosa.

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, 2017.

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 sim 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 innovative antibacterial treatments against multi-drug resistant ("MDR") gram-negative infections. We are developing plazomicin, our lead product candidate, for the treatment of serious bacterial infections, including complicated urinary tract infection ("cUTI"), blood stream infections ("BSI") and other infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae ("CRE"). In 2013, the Centers for Disease Control and Prevention ("CDC") 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 ("WHO") identified CRE as a Global Priority 1 Pathogen: Critical Need for Research and Development of New Antibiotics. Our second antibacterial candidate is C-Scape, an orally-administered combination of clavulanate and ceftibuten, which targets serious bacterial infections due to expanded spectrum beta-lactamases ("ESBL") producing Enterobacteriaceae. In 2017, the WHO identified ESBL as a Global Priority 1 Pathogen: Critical Need for Research and Development of New Antibiotics. We also have other programs in early and late preclinical stages focused on other MDR gram-negative infections and additional disease areas.

On May 23, 2017, we announced that the FDA granted Breakthrough Therapy designation ("BTD") for plazomicin for the treatment of BSI caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options. BTD was created by the FDA to expedite the development and review of drugs that target serious or life-threatening conditions. On January 2, 2018, we announced the acceptance of a New Drug Application ("NDA") for substantive review by the U.S. Food and Drug Administration ("FDA") for plazomicin, seeking approval to treat cUTI, including acute pyelonephritis ("AP") and BSI due to certain Enterobacteriaceae in patients who have limited or no alternative treatment options. The NDA is supported by data from two Phase 3 clinical trials, EPIC (Evaluating Plazomicin In cUTI) and CARE (Combating Antibiotic Resistant Enterobacteriaceae). The FDA has accepted review of the NDA and has granted the NDA Priority Review as well as set a Prescription Drug User Fee Act ("PDUFA") target action date of June 25, 2018. As part of our NDA review process, on May 2, 2018, the Antimicrobial Drugs Advisory Committee ("Committee") of the FDA voted 15 to 0 in plazomicin's favor that there was substantial evidence of the safety and effectiveness for the treatment of cUTI and 11 to 4 against plazomicin that there was not substantial evidence for the treatment of BSI in patients with limited or no treatment options. The FDA is not bound by the Committee's votes but takes its input into consideration when reviewing marketing applications.We expect a commercial launch of plazomicin in the United States in 2018, if our NDA is approved. We also intend to submit an

application for marketing authorization (“MAA”) in the European Union (“EU”) in 2018.

Plazomicin received Qualified Infectious Disease Product (“QIDP”) designation from the FDA, which provides incentives for the development of new antibiotics, including priority review and an extension by an additional five years of any existing non-patent market exclusivity the product may be awarded upon approval. We have global commercialization rights to plazomicin, which has patent protection in the United States currently estimated from 2030 to 2032.

Plazomicin has been evaluated in two Phase 3 clinical trials, entitled EPIC and CARE. The EPIC study was a Phase 3 trial of plazomicin for the treatment of patients with cUTI and AP and enrolled 609 patients. In the EPIC trial, plazomicin successfully met 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 outcomes at the Test-of-Cure (Day ~17) statistically favored plazomicin. 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 also generally well tolerated with no new safety concerns identified in the EPIC trial.

The CARE study was a Phase 3 resistant pathogen trial designed to evaluate the efficacy and safety of plazomicin in patients with serious bacterial infections due to CRE. The CARE trial enrolled 69 patients, comprised of 39 patients enrolled in Cohort 1, comparing plazomicin to colistin-based therapy in patients with BSI 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 who were not eligible for Cohort 1. In Cohort 1 of the CARE trial, a lower rate of mortality at Day 28 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.

According to government agencies and physician groups, including the CDC, the Infectious Disease Society of America, and the WHO, one of the greatest needs for new antibiotics is to treat MDR Enterobacteriaceae, including ESBL producing isolates and CRE. CRE leads to mortality rates of up to 50% in patients with BSI. We estimate that there were approximately 180,000 cases of CRE infections in the United States and five major markets in the EU in 2016 including France, Germany, Italy, Spain and the United Kingdom, which we refer to as the EU 5. Based on the significant increase in resistance rates in recent years, we anticipate CRE will continue to spread and remain a major health problem. Governments, in collaboration with the private sector, have begun to respond by advancing regulatory reform and economic incentives to spur development of new antibiotics.

Plazomicin is a novel intravenous aminoglycoside antibiotic. Aminoglycosides have been used successfully for the treatment of serious infections for more than 50 years. However, clinical resistance to currently marketed aminoglycosides has increasingly limited their utility. We developed plazomicin by chemically modifying sisomicin, a naturally occurring aminoglycoside, in order to overcome common aminoglycoside resistance mechanisms. In MDR Enterobacteriaceae, including ESBL-producing isolates and CRE, plazomicin remains active where most other antibiotics, including commercially available aminoglycosides, have limited potency due to resistance.

In January 2018, we announced positive Phase 1 top-line results for our orally-administered antibacterial candidate, C-Scape, which is a combination of ceftibuten, an approved third generation cephalosporin, and clavulanate, an approved -lactamase inhibitor. We believe that C-Scape has the potential to address a serious unmet need for an effective oral treatment for patients with cUTI, including AP, caused by ESBL-producing Enterobacteriaceae. The Phase 1 top-line results demonstrated that, in healthy subjects, C-Scape was well tolerated across all doses studied, with no drug-drug interactions observed between the previously approved compounds when dosed in combination. Since completing the Phase 1 clinical trial, pharmacokinetic/pharmacodynamic (PK/PD) modeling using Phase 1 PK and preclinical study data indicate that additional development work is needed, including an additional Phase 1 Clinical Pharmacology study. Given the additional work necessary to optimize the likelihood of Phase 3 and commercial success, our single Phase 3 study will not be initiated in 2018 as we previously had anticipated. Our C-Scape program is funded in part by a contract with the Biomedical Advanced Research and Development Authority (“BARDA”) for up to $18.0 million, of which $12.0 million is committed. The C-Scape drug combination was granted QIDP designation by the FDA for the treatment of cUTI, including AP, in January 2017. We currently plan to leverage a 505(b)(2) regulatory path to support the potential initiation of a single pivotal phase 3 trial.

Our research and development pipeline includes small molecule and antibody programs that target gram-negative pathogens as well as other disease areas. These programs include our collaboration with the Bill & Melinda Gates Foundation which provides for up to $20.5 million in grant funding and equity investments, of which $13.2 million in funding and a $10.0 million equity investment has been provided to further develop our antibody platform and discover monoclonal antibody candidates against gram-negative bacteria, including those that cause neonatal sepsis.

Financial Overview

Contract Revenue

Our contract revenue represents services performed for the development of our product candidates under non-profit foundation and U.S. government contracts (collectively, the "Revenue Contracts"). For the three-month periods ended March 31, 2018 and 2017, contract revenue was $2.1 million and $7.5 million. We have derived all of our revenue to date from funding provided under the Revenue Contracts in connection with the development of our 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 period ended March 31, 2018, total revenue recognized under the Gates Foundation contract was $0.6 million. We did not recognize any revenue from the Gates Foundation for the three-month period ended March 31, 2017.

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 (the "BARDA-plazo Contract") provides for payments to us based on direct costs incurred and allowances for overhead, plus a fee, where applicable. As of March 31, 2018 the total committed funding under our BARDA-plazo Contract is $124.4 million. Through March 31, 2018, a total of $124.3 million was recorded as revenue under this BARDA-plazo Contract, with $0.1 million of funding remaining.

In September 2017, BARDA awarded us funding to support the development, including Phase 1 and Phase 3 clinical studies and manufacturing and analytical testing, of C-Scape. This 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 this contract is $12.0 million, including subsequent option periods that, if exercised, would bring the total value of the award to $18.0 million. Through March 31, 2018, a total of $2.4 million was recorded as revenue under this BARDA contract, with $9.6 million of funding remaining

For the three-month periods ended March 31, 2018 and 2017, total revenue recognized under the BARDA contracts was $1.5 million and $7.1 million, respectively.

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, pre-approval commercial supply 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. Prior to any approval of plazomicin, all commercial manufacturing of inventory has been recognized as research and development expense.

Further, 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 expect to continue to incur substantial research and development expenses in the future as we continue to support plazomicin, C-Scape development and our pre-clinical pipeline.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, finance, audit and tax services, IT software, projects and services, commercialization activities, 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, 2017.

During the three-month period ended March 31, 2018, 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, 2017.

Results of Operations

Comparison of the Three-Month Period Ended March 31, 2018 and 2017

	Three Months Ended March 31,		
	2018	2017	Change
Contract revenue	$2,143	$7,463	$(5,320)
Operating expenses			
Research and development	30,911	18,597	12,314
General and administrative	15,069	6,751	8,318
Total operating expenses	45,980	25,348	20,632
Loss from operations	(43,837)	(17,885)	(25,952)
Interest expense	(604)	(706)	102
Change in warrant and derivative liabilities	(2,531)	(14,956)	12,425
Loss on debt extinguishment	(819)	—	(819)
Other income, net	562	288	274
Net loss	$(47,229)	$(33,259)	$(13,970)

Contract Revenue

Contract revenue in each period related solely to funding pursuant to our Revenue Contracts. Contract revenue decreased $5.4 million to $2.1 million in the three-month period ended March 31, 2018 from $7.5 million in the comparable period in 2017. This decrease was primarily due to lower BARDA contract revenues related to the plazomicin program.

Research and Development Expenses

Research and development expenses increased $12.3 million to $30.9 million in the three-month period ended March 31, 2018 from $18.6 million in the comparable period in 2017. This was primarily due to increases of $9.8 million in personnel and facility related costs as net headcount increased by 73 employees in our research and development organization since March 2017 these increases in personnel and facility related costs include $0.5 million for stock-based compensation expense, $1.7 million in the external expenses related to our plazomicin program, mainly attributable to the manufacturing of plazomicin, $0.4 million in external expenses related to C-Scape, and $0.4 million in external non-clinical costs for other research programs.

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.

	Three Months Ended March 31,		
	2018	2017	Change
	(in thousands)		
Research and development expenses by program:			

Plazomicin	$19,462	$12,244	$7,218
C-Scape	4,837	2,650	$2,187
Other research programs	6,612	3,703	2,909
Total research and development expenses	$30,911	$18,597	$12,314

General and Administrative Expenses

General and administrative expenses increased $8.3 million to $15.1 million for the three-month period ended March 31, 2018 from $6.8 million for the comparable period in 2017. The increase in general and administrative expenses was primarily due to an increase of $5.5 million in personnel and facility related costs, which includes $0.9 million for stock-based compensation expense, as net headcount increased by 39 employees since March 2017, an increase of $2.2 million in costs to prepare for commercialization of plazomicin and $0.6 million in consulting and professional fees.

Interest Expense

Interest expense was $0.6 million and $0.7 million for the three-month periods ended March 31, 2018 and 2017, respectively.

Change in Warrant and Derivative Liabilities

Change in warrant and derivative liabilities decreased by $12.5 million to $2.5 million for the three-month period ended March 31, 2018 from a $15.0 million expense for the comparable period in 2017. 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.

Liquidity and Capital Resources

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 ATM equity offering program, private placements of our equity securities and certain debt-related financing arrangements. In addition, we have historically received funding provided under U.S. government contracts and non-profit foundations in connection with the development of our product candidates.

Our plazomicin and C-Scape programs have been funded in part with contracts from BARDA. Our other programs are currently funded primarily with company funds. Historically, our preclinical programs have received funding support from organizations such as the Gates Foundation, the National Institutes of Health, the U.S. Department of Defense, the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X") 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 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 February 26, 2018, we terminated the loan and security agreement with Solar Capital Ltd. and repaid $20.9 million of the outstanding principal and interest.

On April 7, 2015, we entered into a Common Stock 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. During the three-month period ended March 31, 2018, we sold 2,144,454 shares of common stock under the Sales Agreement, at a weighted-average price of approximately $11.51 per share for aggregate gross proceeds of $24.7 million and aggregate net proceeds of $24.0 million. As of March 31, 2018, we had sold 3,250,003 shares of common stock under the Sales Agreement for aggregate gross proceeds of $30.0 million and aggregate net proceeds of $29.2 million. No shares remain available for sale under the Sales Agreement.

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").

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.

In September 2017, we were awarded a contract ("C-Scape Contract") valued at up to $18.0 million in grant funding from BARDA to support the development of C-Scape. The C-Scape Contract includes a base period with committed funding of $12.0 million and subsequent option periods that, if exercised, would bring the total value of the award to $18.0 million.

On February 26, 2018, we entered into a new loan and security agreement with Silicon Valley Bank, pursuant to which Silicon Valley Bank agreed to make available to us term loans with an aggregate principal amount of up to $50.0 million, $20.9 million of which was used to repay our loan with Solar Capital Ltd., $4.1 million of which was provided to us on February 26, 2018 and $25.0 million of which remains available for borrowing.

On February 27, 2018, we filed an amended Registration Statement on Form S-3 (the "2018 Shelf Registration Statement") covering the offering of up to $250.0 million of common stock, preferred stock, debt securities, warrants and units. In addition, on February 27, 2018, we filed a prospectus supplement to the 2018 Shelf Registration Statement covering the offering, issuance and sale of up to $50.0 million shares of our common stock in ATM offerings pursuant to a Common Stock Sales Agreement entered into with Cowen and Company, LLC (the "2018 Sales Agreement") on February 27, 2018.

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, C-Scape and other product candidates through preclinical and clinical development, seek regulatory approval, and prepare for, if approved, commercialization. We believe that our existing cash, cash equivalents and short-term investments, together with the additional $25.0 million term loan available under our loan and security agreement with Silicon Valley Bank, will be sufficient to fund our current planned operations for at least the next twelve months from the filing of this report. We plan to raise additional funds through equity or debt financing, government contracts, third party collaborations or other sources to permit additional investments in the commercialization of plazomicin and continued research and development efforts. These funding sources may not be available at terms acceptable to us or at all. If we are unable to raise additional funding, a reduction in the scope of our research and development programs and other operations may become necessary. 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 in preparation for commercial launch of plazomicin expected in 2018, if our NDA is approved by the PDUFA date. 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.

Cash Flows

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Cash Flows from Continuing Operations:		
Net cash used in operating activities	$(46,712)	$(13,418)
Net cash used in investing activities	(30,778)	(68,688)
Net cash provided by financing activities	25,740	781
Net decrease in cash, cash equivalents and restricted cash	$(51,749)	$(81,325)

Cash Flows from Operating Activities

Net cash used in operating activities was $46.7 million for the three-month period ended March 31, 2018. The primary use of cash was to fund our operations related to the research and development of our product candidates and to prepare for commercialization of plazomicin. Our net loss from operations in the three-month period ended March 31, 2018 of $47.2 million was partially offset by non-cash charges of $4.2 million for stock-based compensation, $2.5 million for the revaluation of the warrant and derivative liabilities, $0.5 million for depreciation and amortization, $0.1 million for non-cash interest expense, $0.8 million for the loss on debt extinguishment and a change in net operating assets and liabilities of $7.6 million. The change in net operating assets and liabilities was primarily due to an increase in contract receivables, an increase in 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, and increase in accounts payable and accrued liabilities partially offset by an increase in deferred revenue, as a result of the Advance Funds received under the grant agreement with the Gates Foundation.

Net cash used in operating activities was $13.4 million for the three-month period ended March 31, 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 three-month period ended March 31, 2017 of $33.3 million was partially offset by non-cash charges of $15.0 million for the revaluation of the warrant and derivative liabilities, $0.1 million for depreciation and amortization, $0.2 million for non-cash interest expense, $2.9 million for stock-based compensation, and a change in net operating assets and liabilities of $1.7 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 a decrease in contract receivables.

Cash Flows from Investing Activities

Net cash used in investing activities was $30.8 million for the three-month period ended March 31, 2018. The net cash used in investing activities during the three-month period ended March 31, 2018 is primarily a result of purchases in excess of maturities of short-term investments of $29.5 million and purchases of property, plant and equipment of $1.3 million related to expansion at our corporate headquarters and to facilitate our research and development activities.

Net cash used in investing activities was $68.7 million for the three-month period ended March 31, 2017. The net cash used in investing activities during the three-month period ended March 31, 2017 is primarily a result of purchases in excess of maturities of short-term investments of $67.5 million and purchases of property, plant and equipment of $1.2 million related to our move into new corporate headquarters and to facilitate our research and development activities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $25.7 million for the three-month period ended March 31, 2018. The net cash provided by financing activities during the three-month period ended March 31, 2018 includes $24.0 million of net proceeds, after deducting issuance costs for the sale of common stock through ATM equity offerings in which Cowen and Company, LLC acted as sales agent, $0.1 million from the issuance of common stock pursuant to our equity incentive plans, $24.4 million, net of issuance costs, from the term loan provided by Silicon Valley Bank, partially offset by a $22.8 million principal repayment on the term loans provided by Solar Capital Ltd.

Net cash provided by financing activities was $0.8 million and zero for the three-month periods ended March 31, 2017 and 2016, respectively. The net cash provided by financing activities during the three-month period ended March 31, 2017 includes $0.3 million of proceeds from the exercise of certain warrants issued from the Private Placement and $0.5 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, the advancement of our research and development programs and the preparation for commercialization of plazomicin. We believe that our existing cash, cash equivalents and short-term investments, together with the additional $25.0 million term loan available under our loan and security agreement with Silicon Valley Bank, will be sufficient to fund our current planned operations for at least the next twelve months from the filing of this report.

We plan to raise additional funds through equity or debt financing, government contracts, third party collaborations or other sources to permit additional investments in the commercialization of plazomicin and continued research and development efforts. These funding sources may not be available at terms acceptable to us or at all. If we are unable to raise additional funding, a reduction in the scope of our research and development programs and other operations may become necessary. Our ability to obtain debt financing may be limited by covenants we have made under our loan and security agreement with Silicon Valley Bank and our pledge to Silicon Valley Bank of substantially all of our assets, other than our intellectual property, as collateral. The negative pledge in favor of Silicon Valley Bank 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 and timing of revenues from approved products like plazomicin (if approved);
- 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 and C-Scape;
- 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 any supplemental applications relating to our NDA for plazomicin;
-

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, including potential collaborative arrangements relating to the commercialization of plazomicin outside the United States, if approved; 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 February 27, 2018, except as noted below:

- In February 2018, we entered into a new loan and security agreement with Silicon Valley Bank, pursuant to which Silicon Valley Bank agreed to make available to us term loans with an aggregate principal amount of up to $50.0 million. The previous loan and security agreement with Solar Capital Ltd. with a long-term debt obligation of $22.8 million was repaid in February 2018 and the new long-term debt obligation is comprised of $25.0 million due by February 2024.

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 ended March 31, 2018. 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, 2017.

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 the design and operation of our disclosure controls and procedures as of March 31, 2018, 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 effective at the reasonable assurance level as of March 31, 2018.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the three-months ended March 31, 2018 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, 2017 and 2016 and the three-month period ended March 31, 2018, 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, 2017 and 2016 were $125.6 million and $71.2 million, respectively. Our net losses for the three-month periods ended March 31, 2018 and 2017 were $47.2 million and $33.3 million , respectively. As of March 31, 2018, we had an accumulated deficit of $420.1 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-commercial launch activities for plazomicin, and continue the development of our other product candidates, including C-Scape. 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 products, 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 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;
- the findings and questions of the FDA if any, during its review of our NDA for plazomicin, and our ability to promptly and adequately address any such findings or questions;
- satisfying pre- or post-approval conditions or suggestions, if any, based on feedback and discussions with the 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 or related diagnostic assays 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 March 31, 2018, we had working capital of $138.7 million and unrestricted cash, cash equivalents and short-term investments of $144.0 million. We expect that our existing cash, cash equivalents and short-term investments, together with the additional $25.0 million term loan available under our loan and security agreement with Silicon Valley Bank, will be sufficient to fund our current planned operations for at least the next twelve months from the filing of this report.

We plan to raise additional funds through equity or debt financing, government contracts, third party collaborations or other sources to permit additional investments in the commercialization of plazomicin and continued research and development efforts. These funding sources may not be available at terms acceptable to us or at all. If we are unable to raise additional funding, a reduction in the scope of our research and development programs and other operations may become necessary. Our ability to obtain debt

financing may be limited by covenants we have made under our loan and security agreement with Silicon Valley Bank and our pledge to Silicon Valley Bank of substantially all of our assets, other than our intellectual property, as collateral. The negative pledge in favor of Silicon Valley Bank 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 and timing of revenues from approved products like plazomicin (if approved);
- 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 and C-Scape;
- 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 any supplemental applications relating to our NDA for plazomicin;
- 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, including potential collaborative arrangements relating to the commercialization of plazomicin outside the United States, if approved; 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 businesses, products and technologies. We currently have no 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 submitted an NDA for plazomicin in October 2017 and we announced acceptance by the FDA in January 2018. We plan on a commercial launch of plazomicin in the U.S. in 2018, if our NDA is approved. We also plan to submit an MAA to the EMA for plazomicin in 2018.

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") or 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 certain patients dosed with plazomicin; the plazomicin IVD assay is intended to measure levels of plazomicin in the blood so such patients can receive safe and efficacious doses of plazomicin.

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 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. Moreover, IVD assays may not be readily or economically available in all territories where plazomicin could ultimately be commercialized.

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. Failure to have a drug management assay available for plazomicin could impact our ability to launch or optimize commercialization of 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 FDA-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, (the "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.

In October 2017, we submitted an NDA to the FDA for plazomicin seeking approval to treat cUTI, including AP, and BSI due to certain Enterobacteriaceae in patients who have limited or no alternative treatment options. The FDA has accepted the NDA for substantive review and set a PDUFA target action date of June 25, 2018. On May 2, 2018, the Antimicrobial Drugs Advisory Committee of the FDA voted 15 to 0 in plazomicin's favor that there was substantial evidence of the safety and effectiveness for the treatment of cUTI and 11 to 4 against plazomicin that there was not substantial evidence for the treatment of bloodstream infections in patients with limited or no treatment options. Although advisory commitees provide recommendations to the FDA, the FDA itself makes final decisions on issues related to plazomicin. This is the first NDA we have submitted and we have not previously had any NDAs accepted for filing or submitted similar drug approval filings to comparable foreign authorities, for any product candidate. We cannot be certain that plazomicin will receive regulatory approval in a timely manner, or at all. Further, plazomicin may not receive regulatory approval even though it was successful in certain clinical trials and even when an advisory committee votes in favor of its approval. 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 clearance or approval of an IVD assay or related diagnostic to be used with plazomicin, 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;
- 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 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, if our NDA for plazomicin is approved, we anticipate the U.S. label will indicate that plazomicin is for use in patients with infections that have limited or no alternative 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, a narrower patient population, or restrictions in connection with a TDM, 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 other pipeline candidates, or how resistance could spread, which could affect the revenue potential for plazomicin, C-Scape or future products.

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 and C-Scape 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 regulatory approval, 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 reasonably 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 sales and marketing efforts, including the effectiveness of the sales and marketing efforts of any collaboration partners, if any;
- the strength of our marketing and distribution support, including the strength of marketing and distribution support of any collaboration partners, if any;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved risk evaluation and mitigation strategy;
- whether and how the product is designated under physician treatment guidelines for particular infections;
- continued development of MDR infections such as CRE;
- 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 have applied for a a New Technology Add-On Payment ("NTAP") from the Centers for Medicare and Medicaid Services ("CMS") for plazomicin. On April 24, 2018, CMS released the Fiscal Year ("FY") 2019 Inpatient Prospective Payment System ("IPPS") proposed rule. The proposed rule raises multiple issues with respect to our NTAP application, including but not limited to our ability to satisfy the three criteria for NTAP eligibility. Comments are due on the proposed rule by June 25, 2018. If granted, we expect NTAP could remain in effect for up to three years depending on if and when we receive this designation. There are no assurances that we will be successful in obtaining an add-on payment for plazomicin or retaining such add-on payment beyond the initial year even if granted.

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. These third parties are located around the world and many of them are outside the United States. 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, including with respect to FDA inspections. 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 and other ingredients 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 and C-Scape. We rely upon third-party manufacturing organizations to manufacture and supply our product candidates and certain raw materials and other ingredients 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 an 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 any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they may not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If any of our contract manufacturers receive warning letters or other notices of violations from the FDA or other regulatory authorities, they may be unable to address the issues raised in such warnings or notices in a timely basis, or at all. This could cause a delay or inability to supply materials or services on a timely basis, or at all. 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 an effective distribution process is not established for plazomicin and any associated IVD assays, which includes cold-chain logistics, our business may be adversely affected.

We do not currently have the infrastructure necessary for distributing pharmaceutical products to patients. We have contracted with a third-party logistics company to warehouse and distribute plazomicin, and we will require plazomicin to be maintained at a controlled temperature for some of the distribution chain. Similarly, Thermo Fisher will be responsible for warehousing and distributing an IVD assay associated with plazomicin, which will also require cold-chain logistics. If we or Thermo Fisher are unable to effectively establish and manage the distribution process of plazomicin or an associated IVD assay, the commercial launch and sales of plazomicin and an associated IVD assay may 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 an 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 an 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 are increasing our sales and marketing capabilities as we prepare for the potential commercialization of plazomicin and 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 are increasing our sales and marketing capabilities as we prepare for the potential commercialization of plazomicin and 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. We currently seek to collaborate with companies that can provide a commercial presence and experience in targeted geographic markets outside of the United States for the commercialization of plazomicin, if approved. 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 could 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, Vabomere™ (meropenem/vaborbactam), which is marketed by Melinta Therapeutics, tigecycline, which is marketed by Pfizer as Tygacil®, other aminoglycosides that are generically available (such as gentamicin, amikacin, tobramycin), and polymixins 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. Tetraphase Pharmaceuticals, Inc. is developing eravacycline for complicated urinary and intra-abdominal infections. Merck & Co., Inc. is developing imipenem/relebactam for certain life-threatening infections caused by MDR strains, including infections due to metallo- b-lactamase producing gram-negative pathogens. Zavante Therapeutics, Inc. is developing ZTI-01 for cUTI. Shionogi is developing cefiderocol for carbapenem-resistant gram-negative pathogens. Allergan plc and Pfizer Inc. continue development of ceftazidime/avibactam (already marketed in the United States) and ceftaroline/avibactam for pneumonia and complicated urinary and intra-abdominal infections. 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 QIDP designation for plazomicin for the treatment of hospital acquired bacterial pneumonia, ventilator-associated pneumonia, complicated intra-abdominal infections, cUTIs, and catheter-related BSI 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 mechanism to help streamline the development programs for certain antibacterial and antifungal drugs that are intended to treat serious or potentially fatal infections in limited populations of patients where unmet need exists due to lack of available therapies. This mechanism, referred to as the limited population pathway for certain antibacterial and antifungal drugs, would permit FDA to rely on data primarily targeting these limited populations and approve such drugs for limited patient populations, notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population. The statement "Limited Population" would appear prominently next to the drug's name in labeling, which would provide notice to healthcare providers that the drug is indicated for use in a limited and specific population of patients. The limited population statement, additional labeling statements describing the data, and FDA review of promotional materials, are intended to help assure these drugs are used narrowly to treat these serious and life-threatening infections while additional evidence is generated to assess safety and effectiveness for broader use. The 21st Century Cures Act 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 us, 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 currently intend to form one or more collaborations relating to the commercialization of plazomicin outside the United States, if approved, and we may also attempt to form other 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 outside the United States, 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 plazomicin or our other 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 for the commercialization of plazomicin outside the United States or for our other product candidates, 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 within or outside of the United States in a timely manner or at all 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 and security 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 February 26, 2018, we entered into a loan and security agreement with Silicon Valley Bank, pursuant to which Silicon Valley Bank agreed to make available to us term loans with an aggregate principal amount of up to $50.0 million, $20.9 million of which was used to repay our loans with Solar Capital Ltd., $4.1 million of which was provided to us on February 26, 2018 and $25.0 million of which remains available for borrowing. 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, and 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 Silicon Valley Bank 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 Silicon Valley Bank 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. Silicon Valley Bank 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 May 2, 2018, we had 234 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 2017, there have been a number of changes to our executive leadership team. In February 2017, we hired our Chief Commercial Officer, Janet Dorling. In March 2017, our former Chief Medical Officer, Ian Friedland, resigned and transitioned to a consulting position. In September 2017, we hired our Chief Business Officer,

Liz Bhatt. And on December 8, 2017, our board of directors appointed Blake Wise as our Chief Executive Officer, effective January 1, 2018. Mr. Wise replaced Kenneth J. Hillan, M.B., Ch.B., whom the Board appointed President, R&D and President of Achaogen, effective January 1, 2018. Mr. Wise previously served as our President and Chief Operating Officer. 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 and management of crucial IT systems may adversely affect our business and results of operations or the effectiveness of our control environment.

We have implemented and are implementing company-wide systems to handle the business and financial processes within our operations and corporate functions. These systems include, for example, Enterprise Resource Planning ("ERP") and Human Resource Information Systems ("HRIS"). Implementations are complex and time-consuming projects that involve substantial expenditures on system software and implementation activities. These implementations also require transformation of business and financial processes in order to reap the benefits of them. Our business and results of operations may be adversely affected if we experience operating problems or cost overruns during the implementation process, or if the systems and the associated process changes do not give rise to the benefits that we expect. If we do not effectively implement, maintain or integrate the ERP and HRIS systems as planned or if the systems do 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.

We rely significantly on information technology and services that utilize the cloud computing environment and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We rely significantly on our information technology to effectively manage and maintain our clinical records, internal infrastructure systems and internal reports. Any failure, inadequacy or interruption of that infrastructure or security lapse of that technology, including cybersecurity incidents, could harm our ability to operate our business effectively. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. A breach in security, unauthorized access resulting in misappropriation, theft, or sabotage with respect to our proprietary and confidential information, including research or clinical data, could require significant capital investments to remediate and could adversely affect our business, financial condition and results of operations.

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 since we no longer constitute an “emerging growth company.” 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. As of December 31, 2017, our management has reported that it believes our internal controls to be effective, and our independent auditors have attested that the operation of our internal controls is effective; however, there can be no assurance that management and our independent auditors will be able to make similar reports in the future.

If in the future 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 implemented a remediation plan to address the underlying causes of the material weakness described above. The remediation plan included:

- 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.

As of March 31, 2018, our management believes our internal controls were effective, and our independent auditors have attested that the operation of our internal controls was effective as of December 31, 2017, however there can be no assurance that management and our independent auditors will be able to make similar reports in the future. We cannot assure that the measures we took in response to this material weakness are sufficient 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.

Recently enacted tax legislation or other changes in tax laws could have a material adverse effect on our business, financial condition and results of operations.

Recently enacted legislation has significantly changed U.S. federal income tax laws, including by reducing the U.S. corporate income tax rate and introducing new rules relating to international taxation, and could have an adverse effect on our business, financial condition and results of operations. The legislation is complex and is unclear in many respects, is subject to potential amendments and technical corrections, and is subject to interpretation and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. We will continue to evaluate the effect of the various domestic and international provisions of this legislation and any additional interpretive guidance that is issued.

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 products has been funded in significant part through contracts 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 and from NIAID. Contracts funded by the U.S. government and its agencies 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. government 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 contracts 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 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 contracts. 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 contracts 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 ("IPR") 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.). 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.

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 contracts 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 contracts 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 that 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, 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.

In January 2018, we announced the FDA accepted for substantive review our NDA for plazomicin, seeking approval to treat cUTI, including AP, and BSI in patients who have limited or no alternative treatment options. FDA has granted the NDA Priority Review and set a PDUFA target action date of June 25, 2018. Other than the NDA for plazomicin, 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. An 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 presidential 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. It is difficult to predict how these Executive Orders 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 Liechtenstein), 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 with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune diseases and other immune dysfunctions 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 is suspended from January 1, 2016 to December 31, 2019, and, absent further legislative action, will be reinstated starting January 1, 2020;
- 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. We expect that the current administration and U.S. Congress may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

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 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. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation

of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that governmental programs 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 U.S. 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;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products, 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, healthcare reform legislation has strengthened these laws. For example, the 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 IVD assay or related diagnostic;
- 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 May 2, 2018, 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.

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. During the three-month period ending March 31, 2018, we sold 2,144,454 shares of common stock under the Sales Agreement, at a weighted-average price of approximately $11.51 per share for aggregate gross proceeds of $24.7 million and aggregate net proceeds of $24.0 million. As of March 31, 2018, we had sold 3,250,003 shares of common stock under the Sales Agreement for aggregate gross proceeds of $30.0 million and aggregate net proceeds of $29.2 million. No shares remain available for sale under the Sales Agreement. 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. On February 27, 2018, we filed an amended Registration Statement

on Form S-3 (the "2018 Shelf Registration Statement") covering the offering of up to $250.0 million of common stock, preferred stock, debt securities, warrants and units. In addition, on February 27, 2018, we filed a prospectus supplement to the 2018 Shelf Registration Statement covering the offering, issuance and sale of up to $50.0 million shares of our common stock in ATM offerings pursuant to a Common Stock Sales Agreement entered into with Cowen and Company, LLC (the "2018 Sales Agreement") on February 27, 2018.

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 pursuant to the 2018 Sales Agreement, 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 May 2, 2018 , we have outstanding a total of 44,796,291 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 (our “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 March 31, 2018, 8,859,227 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 May 2, 2018, certain holders of 1,746,461 shares of our 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 specifies 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.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	File No.	Date Filed with the SEC	Exhibit Number	Provided Herewith
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	Loan and Security Agreement, dated February 26, 2018, by and between the Company and Silicon Valley Bank.	10-K	001-36323	2/27/2018	10.28	
10.2#	Form of Executive Severance Agreement.					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

# Indicates management contract or compensatory plan.

*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.

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: May 7, 2018 ACHAOGEN, INC.

By: /s/ Blake Wise
Blake Wise
Chief Executive Officer

(principal executive officer)

Date: May 7, 2018 By: /s/ Tobin C. Schilke
Tobin C. Schilke
Chief Financial Officer

(principal financial and accounting officer)