Achaogen Inc
Form 10-Q
May 11, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

or

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

For the transition period from to

Commission File Number: 001-36323

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.)
7000 Shoreline Court, Suite 371 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 x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of May 1, 2015 there were 18,049,934 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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Item 3 through 5 of Part II have been omitted because they are not applicable with respect to the current reporting period.

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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, 2015 (unaudited)	December 31, 2014 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$22,933	$18,881
Short-term investments	38,713	44,798
Contracts receivable	4,472	5,234
Prepaids and other current assets	605	520
Total current assets	66,723	69,433
Property and equipment, net	648	725
Restricted cash	127	127
Deposit and other assets	47	37
Total assets	$67,545	$70,322
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$3,947	$2,122
Accrued liabilities	3,254	3,266
Other current liabilities	132	128
Total current liabilities	7,333	5,516
Deferred rent	160	193
Total liabilities	7,493	5,709
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.001 par value, 290,000,000 shares authorized at March 31, 2015 and December 31, 2014; 18,049,934 and 17,907,135 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	18	18
Preferred stock, $0.001 par value, 10,000,000 shares authorized and zero shares issued and outstanding at March 31, 2015 and December 31, 2014	—	—
Additional paid-in-capital	215,117	213,527
Accumulated deficit	(155,079)	(148,900)
Accumulated other comprehensive loss	(4)	(32)
Total stockholders' equity	60,052	64,613
Total liabilities and stockholders' equity	$67,545	$70,322

See accompanying notes to condensed consolidated financial statements

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

	Three Months Ended March 31,	
	2015	2014
Contract revenue	$4,880	$5,988
Operating expenses		
Research and development	7,879	6,605
General and administrative	3,231	2,617
Total operating expenses	11,110	9,222
Loss from operations	(6,230)	(3,234)
Interest expense	—	(179)
Other income (expense), net	51	(42)
Net loss	$(6,179)	$(3,455)
Basic and diluted net loss per common share	$(0.34)	$(1.00)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	17,998,390	3,456,088

See accompanying notes to condensed consolidated financial statements

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

	Three Months Ended March 31,	
	2015	2014
Net loss	$(6,179)	$(3,455)
Other comprehensive loss:		
Net unrealized gain on available-for-sale securities	28	—
Total comprehensive loss	$(6,151)	$(3,455)

See accompanying notes to condensed consolidated financial statements

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

	Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(6,179)	$(3,455)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	99	88
Amortization of premium on short-term investments	167	—
Stock-based compensation expense	761	367
Revaluation of convertible preferred stock warrant liability	—	42
Non-cash interest expense relating to notes payable	—	72
Change in operating assets and liabilities:		
Contracts receivable	762	1,203
Prepaids and other assets	(30)	1,715
Accounts payable and accrued liabilities	1,813	211
Other liabilities	(29)	(1)
Net cash (used in) provided by operating activities	(2,636)	242
Cash flows from investing activities:		
Purchase of property and equipment	(22)	(7)
Purchase of short-term investments	(1,997)	—
Maturities of short-term investments	7,943	—
Net cash provided by (used in) investing activities	5,924	(7)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	—	75,181
Proceeds from the exercise of stock warrants	—	2
Proceeds from the exercise of stock options, net of repurchases	764	—
Repayment of notes payable	—	(1,219)
Net cash provided by financing activities	764	73,964
Net increase in cash and cash equivalents	4,052	74,199
Cash and cash equivalents, beginning of period	18,881	10,738
Cash and cash equivalents, end of period	$22,933	$84,937
Supplemental disclosures of noncash investing and financing information		
Conversion of convertible preferred stock into common stock	$—	$132,278
Reclassification of warrant liability to additional paid-in-capital	$—	$286
Deferred initial public offering issuance costs	$—	$1,238

See accompanying notes to condensed consolidated financial statements.

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Achaogen, Inc.
March 31, 2015
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 clinical-stage biopharmaceutical company committed to the discovery, development, and commercialization of novel antibacterial drugs to treat multi-drug resistant gram-negative infections. The Company is developing plazomicin, its lead product candidate, for the treatment of bacterial infections due to Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. The Company is running an ongoing Phase 3 CARE (Combating Antibiotic Resistant Enterobacteriaceae) trial of plazomicin and the first patients were enrolled in the trial in the third quarter of 2014. In addition, in the fourth quarter of 2015, the Company plans to commence a pivotal Phase 3 trial of plazomicin for the treatment of patients with complicated urinary tract infections.

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

Reclassifications

Prior period's other expense amounts in the consolidated statements of operations were reclassified to conform to the current year's presentation. Such reclassification did not impact our net loss or financial position.

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and following the requirements of the Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company's financial information. The results of operations for the three-month period ended March 31, 2015 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, 2014 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, 2014 included in the Company's Annual Report on Form 10-K.

Initial Public Offering

In March 2014, the Company completed its initial public offering ("IPO") of shares of its common stock, pursuant to which the Company issued 6,900,000 shares of common stock, which includes 900,000 shares issued pursuant to the over-allotment option granted to its underwriters, and received net proceeds of approximately $73.9 million, after deducting underwriting discounts, commissions and estimated offering expenses. In connection with the completion of the Company's IPO, all shares of convertible preferred stock converted into 10,386,894 shares of common stock and all of the Company's convertible preferred stock warrants were converted into warrants to purchase common stock.

2. Summary of Significant Accounting Policies

Use of Estimates

The accompanying financial statements have been prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures of contingent liabilities. On an ongoing basis, management evaluates its estimates, including those related to clinical trial accruals, fair value of liabilities, common

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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.

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, 2015 and December 31, 2014, cash and cash equivalents consisted of bank deposits, cash, and investments in 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 were reported as a component of net unrealized losses 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 is 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, 2015 and December 31, 2014, the Company had long-term restricted cash of $127,000. The restricted cash, which consists of a money market account with one of the Company's financial institutions, serves as collateral for a letter of credit provided as a security deposit under the Company's facility lease. The facility lease expires on April 14, 2017.

Segment Reporting

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

Customer Concentration

For the three-month periods ended March 31, 2015 and 2014, the Company's revenue has been generated solely from funding pursuant to U.S. government contracts, and accordingly 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 and money market accounts at one financial institution, which at times, may 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. Our 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, 2015 and December 31, 2014, the Company has not experienced any credit losses in such accounts or investments.

Revenue Recognition

The Company recognizes revenue when: (i) evidence of an arrangement exists, (ii) fees are fixed or determinable, (iii) services have been delivered, and (iv) collectability is reasonably assured. The Company currently generates revenue

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entirely from government contracts. Government contracts are agreements that provide the Company with payments for certain types of expenditures in return for research and development activities over a contractually defined period. Revenue from 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. Funds received from third parties under contract arrangements are recorded as revenue if the Company is deemed to be the principal participant in the contract arrangements because the activities under the contracts are part of the Company’s development programs. If the Company is not the principal participant, the funds from contracts are recorded as a reduction to research and development expense. Contracts funds received are not refundable and are recognized when the related qualified research and development costs are incurred and when there is reasonable assurance that the funds will be received. Funds billed and received in advance are recorded as deferred revenue.

Recent Accounting Pronouncements

In January 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-01 “Income Statement - Extraordinary and Unusual Items (Subtopic 225-20) - Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items.” This guidance eliminates from GAAP the concept of extraordinary items and is effective for annual reporting periods, including interim reporting periods, beginning after December 15, 2015, and is applicable to the Company's fiscal year beginning January 1, 2016. Early adoption is permitted. The Company does not anticipate it will have a material impact to its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The ASU's effective date is for interim and annual periods beginning after December 15, 2016. Adoption of the ASU is either retrospective to each prior period presented or retrospective with a cumulative adjustment to retained earnings or accumulated deficit as of the adoption date. Early adoption is not permitted. On April 1, 2015, the FASB voted to propose a one-year deferral to the effective date, but to permit entities to adopt one year earlier if they choose (i.e., the original effective date). The proposal will be subject to the FASB’s due process requirement, which includes a period for public comments. The Company is assessing the potential effects of this ASU on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Topic 205-40), Going Concern. This ASU introduces an explicit requirement for management to assess if there is substantial doubt about an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management must assess if there is substantial doubt about an entity's ability to continue as a going concern within one year after the issuance date. Disclosures are required if conditions give rise to substantial doubt. ASU 2014-15 is effective for all entities in the first annual period ending after December 15, 2016. The Company is currently assessing the potential effects of this ASU on its consolidated financial statements.

Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. 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 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. Because the Company has reported a net loss in all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods. Effective as of the completion of the IPO, all of the Company’s preferred stock was converted to common stock. For purposes of calculating net loss per common share for the three-month period ended March 31, 2014, the preferred stock converted to common stock was included in the net loss per common share calculation on a post-conversion

basis based on the conversion date.

For the three-month periods ended March 31, 2015 and 2014, all potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding because such securities have an antidilutive

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impact due to losses reported (in common stock equivalent shares). Below are listed the potentially dilutive securities outstanding as of March 31, 2015 and 2014, respectively:

	March 31, 2015	2014
Options to purchase common stock	1,993,555	1,772,171
Warrants to purchase common stock	30,024	40,454

In March 2015, warrants to purchase 10,430 shares of common stock with an exercise price of $13.42 expired. Warrants to purchase 30,024 shares of common stock at an exercise price of $11.99 remain outstanding as of March 31, 2015.

3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amount of certain financial instruments, including cash and cash equivalents, contracts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

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

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

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

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

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

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy. Level 3 liabilities that are measured at estimated fair value on a recurring basis consist of convertible preferred stock warrant liabilities and derivative liabilities associated with certain convertible loans.

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As of March 31, 2015 and December 31 2014, 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, 2015			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets				
Cash	$977	$—	$—	$977
Level 1:				
Restricted cash	127	—	—	127
Money market funds	21,956	—	—	21,956
Subtotal	22,083	—	—	22,083
Level 2:				
Corporate debt securities	36,719	4	(8)	36,715
Commercial paper	1,998	—	—	1,998
Subtotal	38,717	4	(8)	38,713
	$61,777	$4	$(8)	$61,773
Reported as:				
Cash and cash equivalents				$22,933
Short-term investments				$38,713
Restricted cash				$127

	December 31, 2014			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets				
Cash	$620	$—	$—	$620
Level 1:				
Restricted cash	127	—	—	127
Money market funds	18,261	—	—	18,261
Subtotal	18,388	—	—	18,388
Level 2:				
Corporate debt securities	44,830	—	(32)	44,798
	$63,838	$—	$(32)	$63,806
Reported as:				
Cash and cash equivalents				$18,881
Short-term investments				$44,798
Restricted cash				$127

All available-for-sale securities held as of March 31, 2015 had maturities greater than three months, but 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 corporate debt obligations that were in unrealized loss positions totaled $21.4 million as of March 31, 2015. 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 corporate debt obligations and has determined that no other-than-temporary impairments associated with credit losses were required to be recognized during the three months ended March 31, 2015.

In connection with the completion of the Company's IPO in March 2014, all of the outstanding warrants to purchase convertible preferred stock converted into warrants to purchase 40,454 shares of common stock at an average exercise price of $12.36 per share. The Company remeasured the estimated fair value of these remaining warrants at the date of

the conversion

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and recorded a $42,000 loss related to the change in estimated fair value as part of interest expense and other, net, and reclassified the estimated fair value of $286,000 to additional paid-in capital.

4. Balance Sheet Components

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2015	December 31, 2014
Accrued clinical and development expenses	$1,717	$1,618
Payroll and related bonus expenses	1,050	1,171
Other	487	477
	$3,254	$3,266

5. License and Collaboration Agreements

Isis Pharmaceuticals

In January 2006, the Company entered into a license agreement with Isis Pharmaceuticals, Inc. (“Isis”). Isis 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 Isis. 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 plazomicin.

Through March 31, 2015, the Company has compensated Isis $7,000,000 in connection with the first three milestones under the license for the first aminoglycoside product candidate. As of March 31, 2015 and December 31, 2014, the Company had no outstanding payments due under the agreement.

6. Government Contracts

Certain of the Company’s drug discovery and development activities are performed under contracts with 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 revenue contracts are recorded as operating expenses in the Company's consolidated statements of operations.

Biomedical Advanced Research and Development Authority

In August 2010, the Company was awarded a contract with the Biomedical Advanced Research and Development Authority (“BARDA”) for the development, manufacturing, nonclinical and clinical evaluation of, and regulatory filings for, plazomicin as a countermeasure for disease caused by antibiotic-resistant pathogens and biothreats. The original contract included committed funding of $27,600,000 for the first two years of the contract and subsequent options exercisable by BARDA to provide additional funding. In September 2012, BARDA modified the contract to increase the total contract committed funding to $43,398,000 through March 2014. In April 2013, the Company was awarded an additional $60,410,000 under the contract to support its Phase 3 clinical trial of plazomicin to increase the total committed funding under this contract to $103,808,000. The Company recorded revenues of $4,841,000 and $5,988,000 under this agreement during the three-month periods ended March 31, 2015 and 2014, respectively.

Defense Threat Reduction Agency

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In November 2012, the Defense Threat Reduction Agency (“DTRA”) terminated for convenience a contract with the Company that provided funding for the Company’s LpxC inhibitor program. In connection with the termination, the Company was seeking payment from DTRA for additional expenses the Company has incurred. In connection with the Company’s claim for payment from DTRA, the Defense Contract Audit Agency has audited the expenses for which the Company is seeking payment. On April 30, 2015, the Company reached a settlement of its claim with DTRA, see Note 9, Subsequent Event.

National Institute of Allergy and Infectious Diseases

In July 2014, the Company was awarded a one-year, $407,000 grant by the National Institute of Allergy and Infectious Diseases (NIAID) to conduct discovery research on novel antibiotics targeting gram-negative bacteria. The Company recorded revenues of $39,000 and zero under this grant during the three-month periods ended March 31, 2015 and 2014, respectively.

7. Borrowings

Oxford Finance and SVB Loan Agreement

In November 2011, the Company entered into a loan and security agreement (the “Loan Agreement”) with Oxford Finance LLC and Silicon Valley Bank (“SVB”), under which the Company borrowed $4,000,000 in November 2011, and the remaining $8,000,000 in April 2012. The loan principal balance, accrued interest and the final payment under the Loan Agreement totaling $4,454,000 were repaid in full in June 2014.

During 2012 and 2011, in connection with the Loan Agreement, 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 estimated fair value of these warrants at the date of issuance was approximately $163,000 and $86,000, respectively, and was recorded as a debt discount and was amortized as interest expense over the term of the loan using the effective-interest method, with the remaining balance charged to interest expense upon loan repayment.

Immediately prior to the closing of the IPO, 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. As of December 31, 2014, these warrants remained outstanding and exercisable.

The Company recorded interest expense related to the loan of zero and $162,000 for the three-month periods ended March 31, 2015 and 2014, respectively.

8. Equity Incentive Plans

2014 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 awards ("RSUs") and other stock-based awards for the purchase of that number of shares of common stock. Effective, January 1, 2015, the compensation committee of the board of directors approved an evergreen increase of 716,285 shares that may be granted in accordance with the terms of the 2014 Plan. As of March 31, 2015, 864,673 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, restricted stock units, 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.

The number of shares of common stock initially

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reserved for issuance under the Inducement Plan was 650,000 shares. As of March 31, 2015, there were no awards issued 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, 2015, the board of directors approved an evergreen increase of 179,071 shares that may be granted in accordance with the terms of the ESPP. As of March 31, 2015, 17,795 shares of common stock have been issued to employees participating in the ESPP, and 306,730 shares are available for issuance under the ESPP.

Amended and Restated 2003 Stock Plan

The Company's Amended and Restated 2003 Stock Plan, referred to herein as 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 when it was terminated as to future awards, 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 board of directors determined the fair value of common stock at the date of grant.

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 December 31, 2014 and 2013 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 Equity Incentive Award Plan (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, 2015, a total of 1,055,799 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 Available for Grant	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)
Balance at December 31, 2014	1,111,470	1,885,372	$7.95	7.62
Additional shares authorized	716,285	—		
Options granted	(320,200)	320,200	$10.99	
Options exercised	—	(142,799)	$5.80	
Options cancelled	69,218	(69,218)	$8.43	
RSUs granted	(75,200)	—		
RSUs cancelled	13,100	—		
Balance at March 31, 2015	1,514,673	1,993,555	$8.57	8.23

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

	Three-Month Periods Ended March 31,	
	2015	2014
Research and development	$312	$151
General and administrative	449	216
Total	$761	$367

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As of March 31, 2015, approximately $6,360,000 of total unrecognized stock-based compensation expense related to unvested stock options is expected to be recognized over a weighted-average period of 3.32 years.

The estimated grant date fair value of employee stock options was calculated using the Black-Scholes valuation model, based on the following assumptions:

	Three Months Ended March 31,	
	2015	2014
Expected term (years)	6.0 years	5.3–6.1 years
Expected volatility	70%	76%–77%
Risk-free interest rate	1.5%–1.8%	1.7%–1.9%
Expected dividend yield	—	—
Expected forfeiture rate	8.3%	7.8%

Restricted Stock Units Granted to Employees

During the three months ended March 31, 2015, the Company granted RSUs to employees to receive 75,200 shares of common stock under the stock plans with a weighted-average estimated grant-date fair value of $11.02 per share. RSUs generally vest annually over a 4-year service period and vesting is contingent on continued service. As of March 31, 2015, there were unrecognized compensation costs of $2,081,000 related to outstanding RSUs, which are expected to be recognized over a weighted-average period of 3.65 years.

A summary of RSU activity is as follows:

	RSU Awards Outstanding		
	Number of RSUs	Weighted-Average Grant Date Fair Market Value	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2014	168,200	$ 9.33	$2,195
RSUs granted	75,200	$ 11.02	
RSUs cancelled	(13,100)	$ 11.17	
Balance, March 31, 2015	230,300	$ 9.78	$2,248

9. Subsequent Event

Effective April 30, 2015, the Company entered into a settlement of its claim with DTRA, a division of the U.S. Department of Defense. The net settlement of $7.1 million payable to the Company, together with sums previously received and entry into the settlement, constitutes payment in full and complete settlement of the amount due to the Company for the complete termination of the contract.

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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, 2014.

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 clinical-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel antibacterials to treat multi-drug resistant ("MDR") gram-negative infections.

Gram-negative bacteria are a subset of bacterial organisms distinguished by the presence of a second cell membrane. We are developing plazomicin, our lead product candidate, for the treatment of bacterial infections due to Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae ("CRE"). Enterobacteriaceae are a family of related gram-negative bacteria that includes Escherichia coli and Klebsiella pneumoniae, and "carbapenem-resistant" strains are those that cannot be effectively treated with carbapenems, a class of antibiotics that is one of the last lines of defense against gram-negative bacteria. In 2013, the Centers for Disease Control and Prevention identified CRE as "nightmare bacteria" and an immediate public health threat that requires "urgent and aggressive action."

Our development plan for plazomicin includes two Phase 3 clinical trials. A single, pivotal Phase 3 trial of plazomicin for the treatment of patients with complicated urinary tract infections ("cUTI") is intended to support a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") for approval of plazomicin. The cUTI trial will be a randomized, double blind, active controlled study in patients with cUTI and acute pyelonephritis and will allow broad enrollment of patients with gram-negative infections. In addition, we've reached agreement with the FDA that this will be a non-inferiority trial comparing plazomicin to meropenem with a 15% non-inferiority margin and a corresponding sample size of approximately 530 patients. We do not currently plan to conduct an additional safety study for plazomicin and we believe the plazomicin cUTI program, comprising the positive Phase 2 cUTI trial and planned Phase 3 cUTI trial, will satisfy the FDA-required safety database. Our Phase 3 CARE (Combating Antibiotic Resistant Enterobacteriaceae) trial is intended to support a supplemental NDA to the FDA for approval of plazomicin for the treatment of blood stream infections and pneumonia caused by CRE. We expect to commence the Phase 3 cUTI trial in the fourth quarter of 2015 with top-line results and an NDA submission expected in the second half of 2017. Our goal is to complete the Phase 3 CARE study and submit a supplemental NDA during the second half of 2018 and we anticipate that our Phase 3 CARE trial will be concluded before the commercial launch of plazomicin in cUTI. We have worked closely with the FDA to amend the protocol for the Phase 3 CARE trial with the goal to improve enrollment. We anticipate this amended protocol will be implemented starting in the second quarter of 2015, and at this time the original Special Protocol Assessment ("SPA") agreed to with the FDA for the Phase 3 CARE trial will no longer be effective. We do not currently intend to request a new SPA.

In 2012, the FDA granted fast track designation for the development and regulatory review of plazomicin to treat serious and life-threatening CRE infections. In 2014, plazomicin received Qualified Infectious Disease Product ("QIDP") designation from the FDA. The QIDP designation was created by the Generating Antibiotic Incentives Now ("GAIN") Act, which was part of the FDA Safety and Innovation Act and provides certain incentives for the development of new antibiotics, including priority review and an additional five years of market exclusivity.

Since commencing operations in 2004, we have devoted substantially all of our resources to identifying and developing our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these functions. In addition to plazomicin, our research team is focused on discovering medicines with novel mechanisms of action for serious infections caused by gram-negative bacteria, including MDR Pseudomonas aeruginosa and MDR Acinetobacter baumannii. We are taking a multifaceted approach to identify new antibacterial agents through our

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research. Our goal is to nominate at least one clinical candidate from our small molecule or therapeutic antibody programs in 2015 and to file an investigational new drug application (“IND”) in 2016.

We are currently financing our operations with the proceeds of our IPO of common stock and funding under our contracts with government agencies. Currently, our plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority ("BARDA"), an agency of the U.S. Department of Health and Human Services. We estimate that our Phase 3 cUTI trial will necessitate additional Achaogen funding of $45 to $50 million from 2015 through 2017, which we anticipate will be primarily accessed via non-diluted sources such as government contracts, grants and debt. Our other programs are currently funded primarily with company funds, although we also have received a relatively small grant from the U.S. National Institutes of Health (the “NIH”). Historically, our preclinical programs have received funding support from organizations in addition to the NIH, such as the U.S. Department of Defense and The Wellcome Trust, a global charitable foundation. We intend to continue to seek further collaborations with government agencies, non-profit foundations, and other research and development funding organizations to support our discovery efforts and advance the product candidates in our pipeline.

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

We have never been profitable and have incurred net losses in each year since the commencement of our operations. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and associated general and administrative costs. We expect to incur substantial losses from operations in the foreseeable future as we advance plazomicin and other product candidates through preclinical and clinical development, seek regulatory approval, and prepare for, and, if approved, proceed to commercialization. We will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Financial overview

Contract Revenue

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

Biomedical Advanced Research and Development Authority (BARDA). We have received funding for our lead product candidate, plazomicin, under a contract with BARDA, an agency of the U.S. Department of Health and Human Services for the development, manufacturing, nonclinical and clinical evaluation of, and regulatory filings for, plazomicin as a countermeasure for disease caused by antibiotic-resistant pathogens and biothreats. Our BARDA contract provides for payments to us based on direct costs incurred and allowances for overhead, plus a fee, where applicable. The total committed funding under our BARDA contract is $103.8 million. The contract also currently includes an option for additional work that has not yet been exercised by BARDA. Potential funding under the unexercised option has not yet been determined, and we anticipate that BARDA will evaluate award of this option during their fiscal year beginning October 1, 2015.

For the three-month periods ended March 31, 2015 and 2014, total revenue recognized under the BARDA Contract was $4.8 million and $6.0 million, respectively. Through March 31, 2015, a total of $64.3 million under the BARDA contract has been recorded as revenue, with $39.5 million remaining available from the funding currently committed under the contract.

Research and Development Expenses

Research and development ("R&D") 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. R&D 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;

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- employee and consultant-related expenses, which include salaries, benefits, stock-based compensation and consulting fees;
- third-party supplier expenses including the cost of acquiring and manufacturing clinical trial and other materials; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, amortization or depreciation of leasehold improvements, equipment and laboratory supplies and other expenses.

We expect to continue to incur substantial expenses for the foreseeable future as we continue research programs and the development of our product candidates. In particular, we expect development costs associated with our plazomicin program to increase significantly as our Phase 3 trials progress. Since product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of research and clinical development, primarily due to the increased size and duration of later-stage clinical trials, we expect that our R&D expenses will increase in the future. In particular, in the fourth quarter of 2015, we plan to commence our pivotal Phase 3 cUTI trial which we estimate will necessitate additional Achaogen funding of $45 to $50 million to complete from 2015 through 2017.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development. We anticipate general and administrative expenses will increase in future periods to support increased R&D activities.

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 in 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, 2014.

During the three-month period ended March 31, 2015, 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, 2014.

Results of Operations

Comparison of the Three-Month Periods Ended March 31, 2015 and 2014

	Three Months Ended March 31,		Change
	2015	2014	
	(in thousands)		
Contract revenue	$4,880	$5,988	$(1,108)
Operating expenses:			
Research and development	7,879	6,605	1,274
General and administrative	3,231	2,617	614
Loss from operations	(6,230)	(3,234)	(2,996)
Interest expense	—	(179)	179
Other income (expense), net	51	(42)	93
Net loss	$(6,179)	$(3,455)	$(2,724)

Contract Revenue

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Contract revenue in each period related solely to funding pursuant to our government contracts. Contract revenue decreased $1.1 million to $4.9 million in the three-month period ended March 31, 2015 from $6.0 million in the comparable period in 2014. This decrease was mainly attributable to a decrease in research and development services related to the Phase 3 CARE clinical trial of plazomicin performed under our BARDA contract during the three-month period ended March 31, 2015.

Research and Development Expenses

Research and development ("R&D") expenses increased $1.3 million to $7.9 million in the three-month period ended March 31, 2015 from $6.6 million in the comparable period in 2014. This was primarily due to increases of $0.7 million in personnel related costs, $0.6 million in consulting and non-clinical costs for research programs other than plazomicin, and $0.8 million in plazomicin manufacturing and non-clinical costs not funded by BARDA, offset by a decrease of $0.8 million in plazomicin clinical costs related to the Phase 3 CARE trial funded by BARDA.

We record R&D expenses by program where directly identifiable. In the table below, we have allocated indirect R&D costs based on time charged directly to programs by R&D employees. Indirect R&D 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,		Change
	2015	2014	
	(in thousands)		
Research and development expenses by program:			
Plazomicin	$5,839	$5,484	$355
Other research programs	2,040	1,121	$919
Total research and development expenses	$7,879	$6,605	$1,274

General and Administrative Expenses

General and administrative expenses increased $0.6 million to $3.2 million for the three-month period ended March 31, 2015 from $2.6 million for the comparable period in 2014. The increase in general and administrative expenses was primarily due to an increase of $0.4 million in costs associated with being a public company including directors and officers liability insurance, directors' fees, and business consulting fees, and an increase of $0.2 million in non-cash stock-based compensation costs.

Interest Expense

Interest expense decreased $0.2 million for the three-month period ended March 31, 2015 from $0.2 million for the comparable period in 2014. The decrease was primarily a result of the pay-off in the second quarter of 2014 of all loans then outstanding.

Other Income (Expense), net

Other income (expense), net increased $0.1 million to $0.1 million for the three-month period ended March 31, 2015 from expense of $42,000 for the comparable period in 2014. Income for the three-month period ending March 31, 2015 relates to income earned on investments and expense for the three-month period ending March 31, 2014 relates to an increase of a preferred stock warrant liability.

Liquidity and Capital Resources

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	Three-Month Periods Ended March 31,	
	2015	2014
	(in thousands)	
Cash Flows from Continuing Operations:		
Net cash provided by (used in) operating activities	$(2,636)	$242
Net cash provided by (used in) investing activities	5,924	(7)
Net cash provided by financing activities	764	73,964
Net increase in cash and cash equivalents	$4,052	$74,199

Net cash used in operating activities was $2.6 million for the three-month period ended March 31, 2015. 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-months period ended March 31, 2015 of $6.2 million was partially offset by non-cash charges of $0.1 million for depreciation and amortization, $0.2 million for amortization of premium on short-term investments and $0.8 million for stock-based compensation. The change in net operating assets of $2.5 million was due to the decrease in accounts receivable $0.8 million due to higher collection in the quarter and the increase in accounts payable and accrued liability of $1.8 million as a result of the timing of our payments.

Net cash provided by operating activities was $0.2 million for the three-month period ended March 31, 2014. The net loss from operations in the three-months ended March 31, 2014 of $3.5 million was more than offset by non-cash charges of $0.6 million and a decrease in net working capital of $3.1 million. Accounts receivable were reduced by $1.2 million due to earlier receipt of payment on our BARDA contract and prepaids and other assets decreased $1.7 million due to the one-time reclassification of prepaid IPO expenses against the gross IPO proceeds received in March.

Net cash provided by investing activities for the three-month period ended March 31, 2015 is a result of maturities in excess of purchases of short-term investments of $5.9 million. Other uses of net cash in both periods resulted from purchases of property, plant and equipment to facilitate our increased research and development activities.

Net cash provided by financing activities was $0.8 million and $74.0 million for the three-month periods ended March 31, 2015 and 2014, respectively. The net cash provided by financing activities during the three-month period ended March 31, 2015 were proceeds from stock options exercised. The net cash provided by financing activities during the three-month period ended March 31, 2014 was primarily related to proceeds from our recent IPO, which totaled $73.9 million net of issuance costs, partially offset by $1.2 million used for the repayment of notes payable to Oxford Finance LLC and SVB.

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. We believe our existing cash, cash equivalents and short-term investments, combined with the funds from the BARDA contract, will allow us to fund our operating plan through at least the next 12 months.

We do not expect that our current capital resources will be sufficient to enable us to seek marketing approval for plazomicin or commercially launch plazomicin. Additionally, we estimate that our Phase 3 cUTI trial will necessitate additional Achaogen funding of $45 to $50 million and that we will need to raise additional funds to pay for this trial. We anticipate that we will need to raise substantial additional financing in the future to fund our operations, including for obtaining marketing approval for plazomicin. We may obtain additional financing through public or private equity offerings, debt financings, a credit facility, government contracts and/or strategic collaborations. Additional financing may not be available to us when we need it or it may not be available to us on acceptable terms, if at all. In addition, although we currently anticipate being able to generate additional financing through non-dilutive means, we may be unable to do so. 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:

- continued funding under our contract with BARDA, including whether BARDA exercises an option to provide additional funding for plazomicin;
- the size, timing and type of the nonclinical and clinical trials that we decide to pursue in the development of our product candidates, including plazomicin;

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

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 period ended March 31, 2015. For additional information regarding market risk, refer to the Qualitative and Quantitative Disclosures About Market Risk section of our Annual Report on Form 10-K for the year ended December 31, 2014.

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 Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2015, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

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Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Risks Related to Our Business and Capital Requirements

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

We are a clinical-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, 2014 and 2013 and the three months ended March 31, 2015, we derived all of our revenue from government contracts for research and development. Our net losses for the years ended December 31, 2014 and 2013 were $20.2 million and $13.1 million, respectively. Our net losses for the three months ended March 31, 2015 and 2014 were $6.2 million and $3.5 million, respectively. As of March 31, 2015, we had an accumulated deficit of $155.1 million.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue to conduct our Phase 3 CARE (Combating Antibiotic Resistant Enterobacteriaceae) trial of our lead product candidate, plazomicin, initiate and conduct our Phase 3 cUTI (complicated urinary tract infection) trial of plazomicin, seek marketing approval for plazomicin, and continue the development of our other product candidates. Our expenses will also increase substantially if and as we:

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

If our product candidates fail to demonstrate safety and efficacy in clinical trials, do not gain regulatory approval, or do not achieve market acceptance following regulatory approval and commercialization, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and

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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, which is in Phase 3 clinical development. If we are unable to develop, 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. In September 2014, we dosed our first patients in our Phase 3 CARE trial, which we initially planned to serve as our pivotal registration trial for plazomicin. We have not previously conducted a clinical trial of plazomicin in patients with CRE infections, and we have no direct clinical evidence that plazomicin is effective in treating CRE infections in humans. Our Phase 2 trial evaluated the efficacy of plazomicin compared with levofloxacin in patients with cUTI. In March 2015, we announced that we would commence enrollment in a Phase 3 cUTI trial in the fourth quarter of 2015, which we now expect to serve as our registration trial for plazomicin. Our ability to develop, obtain regulatory approval for, and successfully commercialize plazomicin effectively will depend on several factors, including the following:

- successful completion of our registration trial for plazomicin in cUTI and our Phase 3 CARE trial, which will depend substantially upon the satisfactory performance of third-party contractors;
- receipt of marketing approvals from the U.S. Food and Drug Administration (the “FDA”) and similar regulatory authorities outside the United States;
- 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 program includes the development of an in vitro diagnostic (“IVD”) assay which must successfully complete a clinical performance study, conducted concurrently with and utilizing patient samples from our Phase 3 CARE trial of plazomicin, and be approved or cleared for marketing by the FDA and certain other foreign regulatory agencies, contemporaneously with the marketing approval of plazomicin for the treatment of blood stream infections and pneumonia caused by CRE, and then be commercialized concurrently with plazomicin in the associated markets. If we are unable to develop, receive marketing approval for plazomicin or the IVD assay in a timely manner or at all, we could experience significant delays or an inability to commercialize plazomicin for the treatment of blood stream infections and pneumonia caused by CRE, which would materially and adversely affect our business, financial condition, and results of operations.

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. For example, the positive results generated to date in nonclinical and clinical studies for plazomicin do not ensure that our Phase 3 trials will demonstrate similar results. 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.

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The first patient in our Phase 3 CARE trial for plazomicin was enrolled in September 2014 and enrollment has continued at a rate slower than anticipated. In March 2015, based on discussions with the FDA, we amended the protocol for our Phase 3 CARE trial to accelerate the rate of patient enrollment in the Phase 3 CARE trial. The protocol amendments primarily provide for (i) expanded eligibility criteria, (ii) simpler study procedures to reduce the burden on patients and clinical sites and (iii) a change to the primary endpoint to a composite endpoint that includes all-cause mortality and a number of significant disease-related complications at day 28, which is expected to result in a higher event rate and to increase the statistical power of the trial. In addition to the protocol amendments, we are working with the local trial sites to accelerate enrollment in the Phase 3 CARE trial by adding study coordinators and enhancing our local presence by engaging directly with local physicians. We cannot be certain that our protocol amendments or our work at the clinical trial sites, once implemented, will accelerate the patient enrollment rate or overall likelihood of success of our Phase 3 CARE trial. Further, we anticipate this amended protocol will be implemented starting in the second quarter of 2015, and at this time the original SPA agreed to with the FDA for the Phase 3 CARE trial will no longer be effective and we do not currently intend to request a new SPA. In addition, we expect to commence a Phase 3 cUTI trial in the fourth quarter of 2015 with topline line results and an NDA submission expected in the second half of 2017. We cannot be certain that our Phase 3 cUTI trial or our Phase 3 CARE trial, or any other future clinical trials for plazomicin, or other product candidates, will begin on time, not need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all, or that any interim analyses with respect to such trials will be completed on schedule or support continued clinical development of the associated product candidate.

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

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

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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 significantly.

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.

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 continue the clinical development of our lead product candidate, plazomicin, seek marketing approval for 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, 2015, we had working capital of $59.4 million and cash, cash equivalents and short-term investments of $61.6 million. We believe our existing cash, cash equivalents and short-term investments, combined with the funds from the BARDA contract, will allow us to fund our operations through at least the next 12 months. We will require additional funding to conduct both of our Phase 3 trials and we expect our expenses to increase substantially as we prepare for and initiate our Phase 3 cUTI trial of plazomicin. In addition, our recent protocol amendments and other changes to our Phase 3 CARE trial are intended to increase the rate of patient enrollment in this trial; however, if the rate of patient enrollment continues to be slower than anticipated, we may decide to implement further changes to our clinical development plan for plazomicin, in which case, we will need to seek additional funds sooner than planned. In addition, other factors may arise causing us to need additional capital resources sooner than anticipated. We anticipate that we will need to raise substantial additional financing in the future to fund our operations, including for obtaining marketing approval for plazomicin.

We may obtain additional financing through public or private equity offerings, debt financings, a credit facility, government contracts and/or strategic collaborations. Additional financing may not be available to us when we need it or it may not be available to us on acceptable terms, if at all. In addition, although we may generate additional financing through non-dilutive means, these non-dilutive sources of funding may be unavailable on acceptable terms, or at all. 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:

- continued funding under our contract with the Biomedical Advanced Research and Development Authority ("BARDA");
- the rate of progress and cost of our Phase 3 trials, any other clinical trials we may commence, preclinical studies and other discovery and research and development activities;
- the size and type of the nonclinical studies that we decide to pursue in the development of our product candidates, including plazomicin;
- the type, number, costs and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- whether or not we decide to pursue additional or alternative pivotal trials for plazomicin;
- the costs associated with bringing a plazomicin IVD assay to support therapeutic drug monitoring through development, approval, and commercialization;
- the timing of, and costs involved in, seeking and obtaining FDA and other regulatory approvals, including the preparation of a New Drug Application ("NDA") for plazomicin, and any supplemental applications thereto;
- our ability to enter into additional collaboration, licensing or other arrangements and the terms and timing of such arrangements;
- the costs of preparing, filing, prosecuting, maintaining and enforcing any patent claims and other intellectual property rights, including litigation costs and the results of such litigation;
- the emergence of competing technologies and other adverse market developments;

- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- the scope, progress, expansion, and costs of manufacturing our product candidates;

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- our ability to enter into additional government contracts, or other collaborative agreements, to support the development of our product candidates and development efforts; and
- the costs associated with being a public company.

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

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. 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.

Our Phase 3 cUTI trial for plazomicin is subject to a number of specific risks that may affect the timeline and outcome of the trial, including the use of a new comparator drug and our lack of experience with clinical trials in certain foreign countries.

Our Phase 3 cUTI trial for plazomicin is subject to a number of specific risks arising from our clinical program and the design of the trial. Although we have completed a Phase 2 clinical trial demonstrating that plazomicin was as effective as a comparator drug in treating cUTI, the results of our completed Phase 2 cUTI trial were based on a comparison to levofloxacin in treating cUTI and our Phase 3 cUTI trial will compare plazomicin to meropenem. This use of a different comparator may cause our Phase 3 cUTI trial results to be unsuccessful or less favorable than anticipated, particularly if meropenem is more effective than levofloxacin in treating patients with cUTI.

Comparisons to results from other reported clinical trials, including our completed Phase 2 cUTI clinical trial, can assist in evaluating the potential efficacy of plazomicin; however, there are many factors that affect the outcome for patients in clinical trials, some of which are not apparent in published reports, and results from different trials often cannot be reliably compared. Therefore, there is no assurance that the results of our Phase 3 cUTI trial for plazomicin will demonstrate safety and efficacy comparable to the results of trials conducted to date or will be sufficient to attain FDA approval.

See also the risk factor entitled “Serious adverse events or undesirable side effects or other unexpected properties of plazomicin 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.”

Any failure to meet our endpoints in the Phase 3 cUTI trial or adequately address safety concerns would jeopardize our ability to obtain regulatory approval for and commercialize plazomicin on schedule, or at all, and significantly harm our business, financial condition, and prospects.

See also the risk factor entitled “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.”

Our Phase 3 CARE trial for plazomicin is subject to a number of specific risks that may affect the outcome of the trial, including the lack of a prior clinical trial in patients with CRE infections and challenges in enrolling an adequate number of patients with rare infections.

Our Phase 3 CARE trial for plazomicin is subject to a number of specific risks arising from our clinical program and the design of the trial. We have not conducted a clinical trial of plazomicin in patients with CRE infections or with bloodstream infections or pneumonia, who are the subjects of our Phase 3 CARE trial, and we have no direct clinical evidence that plazomicin is effective in treating CRE infections in humans. Our Phase 2 trial demonstrated that plazomicin was as effective as the comparator drug in treating cUTI arising from non-CRE bacteria. Although we believe that plazomicin will be effective in treating CRE infections in humans based upon our nonclinical in vitro and in vivo animal model study results, together with our Phase 2 trial results, these results are not necessarily predictive of the results in humans and we cannot guarantee that plazomicin will demonstrate the expected efficacy in our Phase 3 CARE trial in patients. We also cannot guarantee that the projections made from our pharmacokinetic and pharmacodynamic models we developed from our nonclinical and clinical plazomicin studies will be validated in our Phase 3 CARE trial.

Because our Phase 3 CARE trial for plazomicin is enrolling patients with rare infections, finding a sufficient number of suitable patients with CRE infections to enroll in the trial has been a significant challenge. In addition, we may face competition in enrolling suitable patients as a result of other companies conducting clinical trials for antibiotic product candidates treating similar infections, resulting in slower than anticipated enrollment in our trial. In March 2015, based on

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discussions with the FDA, we amended the protocol for our Phase 3 CARE trial and these amendments are designed to accelerate the rate of patient enrollment in the Phase 3 CARE trial. Continued enrollment delays in this trial may result in increased development costs for plazomicin, or slow down or halt our product development and approval process for plazomicin. We may choose to further revise the enrollment protocol, commence new trials in a different patient population, or take other actions that may result in a substantial change in the clinical development program of plazomicin.

Our Phase 3 CARE trial also involves dosing of patients with plazomicin for longer durations (7–14 days) than in our Phase 1 and 2 trials at the comparable dosage (up to five days), which may lead to additional or more severe adverse events than were reported in our Phase 1 and 2 trials, including as a result of toxicity in the kidneys, inner ear, or hypotension.

See the risk factor entitled “Serious adverse events or undesirable side effects or other unexpected properties of plazomicin 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.”

Our Phase 3 CARE trial is using a superiority design rather than a non-inferiority design. Based on the recently amended protocol amendment, in order to meet our primary endpoint, we must show that plazomicin is superior to the comparator therapy with respect to a composite endpoint that includes all-cause mortality and a number of significant disease-related complications at day 28. This is a different standard than most other antibiotic clinical trials, which are designed to show that the antibiotic is not inferior to the comparator therapy. We may be unable to demonstrate superiority or the anticipated pharmacoeconomic benefits of plazomicin therapy in our Phase 3 CARE trial. Our choice of a "mortality plus" endpoint means that success will depend to a significant degree on the accuracy of our assumptions about the rates of mortality and a number of significant disease-related complications in the comparator and plazomicin arms of our Phase 3 CARE trial. Although we believe we have been conservative in our assumptions, if, for example, patients in the comparator arm of our trial have significantly lower rates of mortality, or rates of applicable disease-related complications, than we expect, we may find that our trial is unfeasible or may have to enroll more patients at additional cost and delay. Further, if we choose to further revise our current trial protocol or complete an alternative pivotal trial for plazomicin, we may not be able to claim certain of the market and label benefits that a successful superiority trial could provide.

See also the risk factor entitled “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.”

Failure to successfully validate, develop and obtain regulatory clearance or approval for our IVD assay could harm our product development strategy for plazomicin for the treatment of blood stream infections and pneumonia caused by CRE.

An important element of our clinical development strategy for plazomicin for the treatment of blood stream infections and pneumonia caused by CRE is the development of an IVD assay to measure levels of plazomicin in the blood, which will enable patients to receive safe and efficacious doses of plazomicin. In collaboration with ARK Diagnostics, Inc. (“ARK”), we are co-developing such an assay for our Phase 3 CARE study, which will be commercialized concurrently with plazomicin, if approved.

IVD assays are 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. An IVD assay that is required for safe and effective use of a drug is referred to as a companion diagnostic. The clinical development of novel therapeutics with a companion diagnostic is complex from an operational and regulatory perspective because of the need for both the drug and the diagnostic to receive regulatory clearance or approval. Specifically, on July 14, 2011, the FDA issued for comment a draft guidance document addressing the development and approval processes for “In Vitro Companion Diagnostic Devices.” According to the draft guidance, for novel therapeutic products such as plazomicin for the treatment of blood stream infections and pneumonia caused by CRE, a companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic. If the regulatory clearance or approval process for our IVD assay is delayed, our ability to commercialize plazomicin for the treatment

of blood stream infections and pneumonia caused by CRE could be delayed until we receive regulatory clearance or approval for the companion diagnostic assay.

It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of our assay during the development and regulatory approval process. We also expect to develop the assay for use on additional analyzers beyond the current Roche Modular P. We, ARK or our future collaborators may encounter difficulties in developing, obtaining regulatory clearance or approval for and manufacturing of the 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 approval for or to obtain market acceptance for and to commercialize our assay or plazomicin for the treatment of blood stream infections and pneumonia caused by CRE.

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

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

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency that plazomicin is safe and effective for the requested indication;
- 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 eventually complete clinical testing and receive approval of an NDA or foreign regulatory filing for plazomicin, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or the applicable foreign regulatory agency also may approve plazomicin for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve the labeling that we believe is necessary or desirable for the successful commercialization of plazomicin. For example, we anticipate the NDA for plazomicin will initially be based on our Phase 3 cUTI trial and that, if approved, we anticipate the U.S. label will indicate that plazomicin is for use in patients with infections that have limited or no alternative antibiotic treatment options. In addition, we believe that the label will include in vitro data against antibiotic resistant pathogens in the microbiology section of the drug label. However, the FDA may approve a label that omits this in vitro data or that limits plazomicin to a more limited indication or narrower patient population, which may harm our ability to

successfully commercialize plazomicin, if approved. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of plazomicin and would materially adversely impact our business and prospects. Any other product candidate we advanced to the marketing approval stage would also be subject to the risks delineated above.

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Serious adverse events or other unexpected properties of plazomicin 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 cause us, an IRB, or regulatory authorities to interrupt, delay or halt our clinical trials and 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 there have been no reports of serious adverse events related to plazomicin in our completed clinical trials. However, our Phase 3 cUTI trial and our Phase 3 CARE trial for plazomicin call for more extended dosing (up to 7 days for our cUTI trial and 7–14 days for our CARE trial) than our Phase 1 and 2 trials at the comparable dosage (up to five days), which may lead to additional or more severe adverse events than were reported in our Phase 1 and 2 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; 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 or how resistance could spread, which could affect the revenue potential for plazomicin.

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

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

resistance. If resistance to plazomicin becomes prevalent, our ability to generate revenue from plazomicin could suffer.

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We will be dependent on ARK to develop and manufacture our IVD assay for our Phase 3 CARE trial for plazomicin for the treatment of blood stream infections and pneumonia caused by CRE, and may become dependent on ARK to commercialize such IVD assay.

We will be dependent on the sustained cooperation and effort of ARK in the development and manufacture of our IVD assay for plazomicin for our Phase 3 CARE trial for the treatment of blood stream infections and pneumonia caused by CRE, including in the generation of analytical data for regulatory approval of such assay. We have also agreed to negotiate with ARK for a commercialization agreement for the IVD assay, and have agreed that any such commercialization agreement would provide ARK with the first right to commercialize the assay in the United States and the EU, and to manufacture and supply the assay worldwide for commercialization, while we would have the first right to commercialize the assay in any other country or territory, in addition to rights to commercialize the assay in the United States and the EU if ARK elects not to do so. Should we enter into such an agreement with ARK, we will be dependent on ARK with respect to such manufacturing and supply and with respect to commercialization in the United States and the EU. This will reduce our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards with respect to the assay.

If ARK does not successfully carry out its contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we may not be able to complete, or may be delayed in completing, the Phase 3 CARE trial and clearance or approval of the assay. We or ARK may encounter difficulties in developing the assay for commercial application in one or more countries, including issues in relation to automation, selectivity/specificity, analytical validation, reproducibility, or clinical validation of such assay. If we do not enter into such a commercialization agreement with ARK, and ARK elects not to participate in the commercialization of the assay in the United States and/or the EU, we would have to find an alternative collaborator, which we may not be able to do on commercially reasonable terms, or at all. If ARK or any such alternative collaborator 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 blood stream infections and pneumonia 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 our Phase 3 trials and 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 multi-drug resistant bacterial infections. 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, 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 parties' 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

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- the development of bacterial resistance to potential product candidates may render them ineffective against target infections.

We withdrew ACHN-975, one of the product candidates from our LpxC inhibitor development program, from clinical trials due to inflammation at the infusion site in some of our Phase 1 subjects and withdrew the IND application for this compound in May 2014. We are actively assessing alternative backup compounds in order to identify candidates that preclinical lab tests will show are effective and likely to exhibit a superior clinical safety profile. We cannot guarantee that these efforts will be successful. If we identify viable product candidates, we would have to submit a new IND application for any compound we seek to advance to clinical trials.

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

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

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

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

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

The availability of adequate third-party coverage and reimbursement for newly 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. The commercial success of our future products in both domestic and international markets depends on whether third-

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party coverage and reimbursement is available 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. 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 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 CRE infections, 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 CRE infections and the high costs of treating antibiotic resistant infections, we are targeting value-based pricing for plazomicin. If hospitals or governmental or other third-party payors do not view the benefits of plazomicin as worth the cost, we will be unable to achieve our pricing and reimbursement objectives and our prospects for revenue and profitability will suffer.

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

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

investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. Our clinical trials must also generally be conducted with products produced under current good manufacturing practice ("cGMP") regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Many of the third parties with whom we contract may also have relationships with other commercial entities, some of which may compete with us. If the third parties conducting our preclinical studies or our clinical trials do not perform their contractual duties or obligations or comply with regulatory requirements we may need to enter into new arrangements with alternative third parties. This could be costly, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable

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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 and other product candidates for us, as well as certain raw materials used in the production thereof. If one of our suppliers or manufacturers fails to perform adequately we may be required to incur significant delays and costs to find new suppliers or manufacturers.

We currently have limited experience in, and we do not own facilities for, manufacturing our product candidates, including plazomicin. We rely upon third-party manufacturing organizations to manufacture and supply our product candidates and certain raw materials used in the production thereof. Some of our key components for the production of plazomicin have a limited number of suppliers. In particular, sisomicin, the aminoglycoside precursor for plazomicin, is supplied by a single manufacturer in China for which we do not have a commercial supply agreement. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacture of our drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. 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 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.

We do not have commercial supply agreements with our suppliers. In the event that we and our suppliers cannot agree to the terms and conditions for them to provide clinical and commercial supply needs, we would not be able to manufacture our product or candidates until a qualified alternative supplier is identified, which could also delay the development of, and impair our ability to commercialize, our product candidates.

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.

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 $5.0 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;

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

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

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

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

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

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

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

We currently have no sales and marketing staff or distribution organization. If we are unable to develop a sales and marketing and distribution capability on our own or through third parties, we will not be successful in commercializing our future products.

We currently have no sales, marketing or distribution organization or history. To achieve commercial success for any approved product candidate, we must either develop a sales, marketing and distribution organization or outsource these functions to third parties. If we rely on third parties for 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 marketed or sold 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.

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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 multi-drug resistant infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, safer or less costly than plazomicin or any other product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

There are a variety of available therapies marketed for the treatment of MDR infections that we would expect would compete with plazomicin, including ceftazadime/avibactam, which is marketed by Actavis plc in the United States (anticipated to be marketed by AstraZeneca PLC outside the United States), 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. Actavis plc and AstraZeneca PLC are developing ceftaroline/avibactam for pneumonia and complicated urinary and intra-abdominal infections. Tetraphase Pharmaceuticals is developing eravacycline for complicated urinary and intra-abdominal infections, as well as pneumonia. The Medicines Company is developing Carbavance™ for cUTI and various infection types due to CRE. Merck is developing relebactam for complicated urinary and intra-abdominal infections, and potentially for pneumonia. 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 Act (the "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. These incentives, along with government contract funding and other incentives for antibiotic research, may result in more competition in the market for new antibiotics.

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

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

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

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

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

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

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

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

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

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

As of March 31, 2015, we had 44 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 our Phase 3 trials, which are being (or are expected to be) conducted at multiple trial sites, and manage any other 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;
- 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 Chief Executive Officer, Kenneth J. Hillan, M.B., Ch.B. 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

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Francisco Bay Area. We are highly dependent on the principal members of our management and scientific staff, particularly our Chief Executive Officer, Dr. Hillan. If we are not able to retain Dr. Hillan 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, including Dr. Hillan, 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 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 2014, there have been a number of changes to our executive leadership team. In February 2014, we hired our Senior Vice President, Chief Financial Officer, Derek Bertocci and in July 2014, we hired our Chief Medical Officer, Ian Friedland, M.D. In November 2014, our former Senior Vice President, Development Operations and Portfolio Management, Becki Filice, resigned from her employment with us for personal reasons. 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.

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 product development programs.

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, the further development of our product candidates could be delayed or our competitive position could be compromised.

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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 IPO in March 2014, we had not been subject to the reporting requirements of the Exchange Act of 1934, as amended (the "Exchange Act"), or the other rules and regulations of the Securities and Exchange Commission (the "SEC") or any securities exchange relating to public companies. We continue to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public company. These areas include corporate governance, corporate control, disclosure controls and procedures and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. However, the expenses associated with being a public company could be material, particularly after we cease to be an “emerging growth company.” Compliance with the various reporting and other requirements applicable to public companies require 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, beginning with our annual report for the year ending December 31, 2015, provide a management report on the internal control over financial reporting. If we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We will be evaluating our internal controls systems to allow management to report on, and eventually our independent auditors will attest to, the effectiveness of the operation of our internal controls. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and eventual auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. The aforementioned auditor attestation requirements will not apply to us until we are no longer an “emerging growth company.”

To date, we have not conducted a review of our internal controls for the purpose of providing a management report on the internal control over financial reporting. We cannot be certain as to the timing of completion of our evaluation, testing and remediation action or the impact of the same on our operations. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, 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

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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 individual acts of some persons, 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.

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

Certain of our existing suppliers 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 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.

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Risks Related to Our U.S. Government Contracts

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

Our development of plazomicin as a countermeasure for diseases caused by antibiotic-resistant pathogens and biothreats is currently being funded in significant part through a contract with BARDA. We have also received funding in the past for other programs from DTRA and from the National Institutes of Health's National Institute of Allergy and Infectious Diseases division. Contracts funded by the U.S. government and its agencies, including our contract with BARDA, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

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

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

For further information, see "Risks Related to Intellectual Property—Provisions in our U.S. government contracts, including our contract with BARDA, may affect our intellectual property rights."

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.

We are dependent on our BARDA contract to fund our Phase 3 CARE trial of plazomicin and, under Option 3 of this contract, BARDA may elect to fund a portion of our Phase 3 cUTI trial. If we do not receive all of the funds under this contract, we may be forced to suspend or terminate either or both of these programs or obtain alternative sources of funding.

We expect a significant portion of the funding for our Phase 3 CARE trial of plazomicin will continue to come from our BARDA contract. In addition, under an unexercised option provided for in our BARDA contract (Option 3), BARDA may elect

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to fund a portion of our Phase 3 cUTI trial. BARDA may terminate our contract at any time for convenience and there can be no assurances that this contract will not be terminated. Changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on supporting the development of antibacterial products such as plazomicin. Although we are currently using a portion of the net proceeds from our IPO to fund our plazomicin development program, any reduction or delay in BARDA funding may force us to suspend or terminate the program or seek alternative funding, which may not be available on non-dilutive terms, terms favorable to us or at all. Further, although our BARDA contract contains an unexercised option for additional funding to support the plazomicin development program, we have not determined the dollar amount of this option and cannot make any assurances as to when or whether the option will be exercised.

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 contract or any future contract we may be awarded may be terminated.

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

Our business is subject to audit by the U.S. government, including under our contracts with BARDA and DTRA, 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;

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- 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.

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

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

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

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

Risks Related to Intellectual Property

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

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

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

pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market any of our

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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.

Furthermore, certain of the patents that we license from the University of Washington are co-owned by Novartis AG. The exclusivity of our license from the University of Washington is therefore subject to Novartis' rights to use the licensed patents and technology for its own purposes, and to grant licenses to others to do so. We therefore rely primarily on our owned patent rights to provide patent protection for our LpxC inhibitor compounds. However, none of these owned patent rights have yet issued, and if these fail to result in issued patents, our competitive position could be adversely affected.

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 interference or derivation proceedings 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,

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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

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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 Isis Pharmaceuticals, Inc., and a portion of the patent portfolio for our LpxC inhibitor program is in-licensed from the University of Washington. 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 Isis Pharmaceuticals, Inc. could materially adversely affect our ability to proceed with the development or potential commercialization of plazomicin as currently planned, while the loss of our license agreement with the University of Washington could materially adversely affect our ability to proceed with any development or potential commercialization of our LpxC inhibitor program.

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

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

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages

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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.

Provisions in our U.S. government contracts, including our contract with BARDA, may affect our intellectual property rights.

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

Recent patent reform 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 “Leahy-Smith Act”) was signed into law. The Leahy-Smith Act 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 USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, 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 Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act 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.

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 our U.S. patents 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.

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

Risks Related to Government Regulation

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

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

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

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

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and any applicable collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Preclinical testing and clinical trials are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical trial could also cause the FDA or us to terminate a clinical trial or require that we repeat it or conduct additional clinical trials. Additionally, data obtained from preclinical studies and clinical trials can be interpreted in different ways and the FDA or other regulatory authorities may interpret the results of our studies and trials less favorably than we do. Even if we believe the preclinical or clinical data for a product candidate is promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials of such product candidates and result in the FDA or other regulatory authorities denying approval of such product candidates for any or all targeted indications. The FDA or other regulatory authorities may determine that plazomicin or any other product candidate that we develop is not effective, or is only moderately effective, or has undesirable or unintended side effects, toxicities, safety profile or other characteristics that preclude marketing approval or prevent or limit commercial use. In addition, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

The regulatory approval process is expensive and may take several years to complete. The FDA and foreign regulatory entities have substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on

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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;
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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;

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- 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. 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. If we or any future collaboration partner are not able to maintain regulatory compliance, we or such collaboration partner, as applicable, will not be permitted to market our future products and our business will suffer. 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 indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- national MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a

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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.
Our product development program for plazomicin is dependent, in part, upon our or a commercial partner’s ability to obtain regulatory clearance or approval of an IVD assay to be used with plazomicin.
Our product development program for plazomicin includes the development of an IVD assay, which must itself successfully complete a clinical performance study conducted concurrently with and utilizing patient samples from the Phase 3 CARE trial of plazomicin, 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.
Before marketing or selling a new medical device, we or our commercial partner must obtain either clearance from the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act (the "FDCA") or approval of a pre-market approval (“PMA”) application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Both the 510(k) and PMA processes can be expensive and lengthy and require the payment of significant fees, unless an exemption applies. The FDA’s 510(k) clearance process usually takes from three to 12 months, but may take longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes at least one year or longer, from the time the application is submitted to the FDA until an approval is obtained. We do not know at present whether the 510(k) clearance process will be available for our IVD assay. If not, we will need to undertake the more costly and more uncertain PMA process.
If the FDA requires us or our commercial partner to go through the PMA process, the introduction of our IVD and plazomicin could be delayed or canceled.
In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of the IVD assay or impact our ability to modify the IVD assay on a timely basis after it has been approved or cleared. Any delay in, or failure to receive or maintain, clearance or approval for our IVD assay could prevent us from generating revenue from plazomicin and the IVD assay and adversely affect our business operations and financial results. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our products and dissuade our customers from using our products.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, results of operations and financial condition could be adversely affected. Moreover, foreign regulatory requirements have become increasingly stringent in recent years, and we may become subject to more rigorous regulation by foreign regulatory authorities in the future. Penalties for a company's noncompliance with foreign governmental regulation could be severe, including revocation or suspension of a company's business license and

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criminal sanctions. In addition, the costs associated with compliance with any domestic or foreign governmental law or regulation imposed in the future may have a material adverse effect on us.

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. 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 Affordable Care Act, among other things:

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs";
- 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;
- 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
- mandates a further shift in the burden of Medicaid payments to the states.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

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

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made

under federal healthcare programs such as the Medicare and Medicaid programs;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;

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- 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 Affordable Care Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the recently enacted Affordable Care Act, 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 Affordable Care Act 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 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 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. Stockholders may also be unable to sell their shares of common stock at prices that are attractive to them due to volatility in the market price of our common stock. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

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announcements relating to our current development program for plazomicin, including any periodic updates relating to timing or rate of enrollment of trial subjects in our Phase 3 CARE trial and our Phase 3 cUTI trial, adverse events, site initiation, and timing of release of interim analyses and final trial results or revisions, modifications to our clinical development plan for plazomicin, including changes to enrollment protocols or additional clinical trials;

- results from, or any delays in, clinical trial programs relating to our product candidates, including our Phase 3 trials;

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- ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;
- 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;
- 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;
- 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;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- healthcare reform measures in the United States;
- 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.

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.

Based on the beneficial ownership of our common stock as of March 31, 2015 (including options exercisable within 60 days of March 31, 2015), our officers and directors, together with holders of 5% or more of our then outstanding common stock and their respective affiliates, beneficially owned approximately 61% of our common stock. Accordingly, these stockholders will 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 significant

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concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

We are an "emerging growth company," as defined in the JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. For example, on April 7, 2015, we entered into a sales agreement with Cowen and Company, LLC ("Cowen") under which, subject to certain conditions, we may offer and sell shares of our common stock having an aggregate offering price of up to $30,000,000 from time to time through Cowen, acting as agent.

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.

Future sales by our existing securityholders 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 trading 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 March 31, 2015, we have outstanding a total of 18,049,934 shares of common stock.

In addition, based on the number of shares subject to outstanding awards under our Amended and Restated 2003 Stock 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, 2015, 4,045,258 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 a registration statement permitting shares of common stock issued in the future pursuant to the 2003 Plan, 2014 Plan, or ESPP to be freely resold by plan participants in the public market, applicable vesting schedules and, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 for shares. 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 increase 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 March 31, 2015, certain holders of 1,746,461 shares of our common stock and warrants exercisable for 30,024 shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act.

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Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Sales of such shares could also cause the trading price of our common stock to decline.

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

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

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director;
- a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;
- an advance notice requirement for stockholder proposals and nominations;
- directors may not be removed without cause and may only be removed with cause by the affirmative vote of 66 2/3% of all outstanding shares of our capital stock with the power to vote in the election of directors;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock with the power to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation.

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

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

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; therefore 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.

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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

On March 17, 2014, we closed our IPO and issued 6,900,000 shares of our common stock at an initial offering price of $12.00 per share. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-193559), which was declared effective by the SEC on March 11, 2014, and a registration statement on Form S-1 (File No. 333-194494), which was effective immediately upon filing on March 11, 2014 . No additional shares were registered. The joint book-running managers for the IPO were Credit Suisse Securities (USA) LLC and Cowen and Company, LLC. The aggregate offering price to the public for the shares sold in the IPO was $82.8 million. We received net proceeds from the IPO of approximately $73.9 million, after deducting underwriting discounts and commissions of approximately $5.8 million and expenses of approximately $3.1 million payable by us. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

In June 2014, we repaid our loans with Oxford and Silicon Valley Bank. None of such payments were direct or indirect payments to any of our directors or officers or their associates, to persons owning 10% or more of our capital stock, or to any of our affiliates.

Other than as described above, there have been no material changes in the planned use of proceeds from our IPO as described in the Prospectus.

(c) Issuer Purchases of Equity Securities

Not applicable.

Item 6. Exhibits.

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

SIGNATURES

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

Date: May 11, 2015

ACHAOGEN, INC.

By: /s/ Derek A. Bertocci
Derek A. Bertocci
Senior Vice President and Chief Financial Officer
(principal financial and accounting officer)

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from				Provided Herewith
		Registrant's Form	File No.	Date Filed with the SEC	Exhibit Number	
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	
10.1	Modification 0019, dated January 6, 2015, to Contract Award issued by the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services, dated January August 30, 2010					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

* 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.