Achaogen Inc
Form 424B4
March 12, 2014
Table of Contents

Index to Financial Statements

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-193559
Registration No. 333-194494

PROSPECTUS

6,000,000 Shares

Common Stock

This is the initial public offering of our common stock. Prior to this offering, there has been no public market for our common stock.

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol AKAO.

The underwriters have an option to purchase a maximum of 900,000 additional shares of common stock from us to cover over-allotments, if any.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 11.

	Price to Public	Underwriting Discounts and Commissions (1)	Proceeds to Achaogen
Per Share	$12.00	$0.84	$11.16
Total	$72,000,000	$5,040,000	$66,960,000

(1) See Underwriting beginning on page 163 for additional information regarding underwriting compensation.

Delivery of the shares of common stock will be made on or about March 17, 2014.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Credit Suisse **Cowen and Company**

William Blair **Needham & Company**

The date of this prospectus is March 11, 2014

Table of Contents

Index to Financial Statements

TABLE OF CONTENTS

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Through and including April 5, 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Table of Contents

Index to Financial Statements

PROSPECTUS SUMMARY

This summary does not contain all of the information you should consider before buying our common stock. You should read the entire prospectus carefully, especially the Risk Factors section beginning on page 11 and our consolidated financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our common stock.

Unless the context requires otherwise, references in this prospectus to Achaogen, we, us and our refer to Achaogen, Inc., and our consolidated subsidiary.

Overview

We are a clinical-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel antibacterials to treat multi-drug resistant, or 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 serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae, or 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 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 a nightmare bacteria and an immediate public health threat that requires urgent and aggressive action. We initiated a Phase 3 superiority trial of plazomicin in the first quarter of 2014. Through the Special Protocol Assessment procedure, the U.S. Food and Drug Administration, or FDA, has agreed that the design and planned analyses of our single pivotal Phase 3 trial adequately address objectives in support of a New Drug Application. We also intend to initiate a supportive efficacy trial in patients with serious CRE infections by the end of 2014. We have received FDA fast track designation for the development and regulatory review of plazomicin to treat serious and life-threatening CRE infections. Our plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority for up to $103.8 million. We have global commercialization rights to plazomicin, which has patent protection in the United States extending through 2031. Plazomicin is the first clinical candidate from our gram-negative antibiotic discovery engine, and we have additional programs in early and late preclinical stages focused on other MDR gram-negative infections.

According to government agencies and physician groups, including the Centers for Disease Control and Prevention, or CDC, and the Infectious Disease Society of America, one of the greatest needs for new antibiotics is to treat infections caused by CRE and other drug-resistant gram-negative pathogens. CRE leads to mortality rates of up to 50% in patients with bloodstream infections. We estimate that there were approximately 110,000 cases of CRE infections in the United States and five major markets in the European Union in 2013, with approximately one-fourth of these being bloodstream infections or pneumonia. Based on the significant increase in resistance rates in recent years, we anticipate CRE will continue to be a major health problem. For example, CDC surveillance data indicates that the rate of carbapenem resistance in *Klebsiella* species increased from 1.6% to 10.4% in the hospital setting in the United States between 2001 and 2011. In Italy, *Klebsiella pneumoniae* carbapenem resistance rates almost doubled from 16% in 2010 to 31% in 2012.

CRE are one of many types of MDR gram-negative pathogens threatening patients. Bacteria such as *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, and extended-spectrum beta-lactamase producing Enterobacteriaceae, the latter of which are organisms with resistance to all beta-lactam antibiotics except for carbapenems, each pose serious resistance threats, according to the CDC, and also drive the need for new, safe, and effective antibiotics. The CDC estimates that the excess annual cost resulting from antibiotic-resistant infections in the United States is as high as $20 billion. According to an estimate from a 2012 study of over 5,500 U.S. patients, the average incremental per-patient hospital cost for antibiotic-resistant healthcare-associated

Table of Contents

Index to Financial Statements

infections, as compared to antibiotic-susceptible infections, was over $15,000. In response to these threats, government agencies such as the Biomedical Advanced Research and Development Authority, the U.S. Department of Defense, and the U.S. National Institutes of Health are providing significant funding to support the discovery and development of new antibiotics.

Our efforts to develop novel drugs that combat MDR gram-negative infections are led by our executive team that has over 60 years of combined industry experience at companies such as Genentech and Gilead Sciences, and a proven track record of leadership, global registration, and lifecycle management for over 20 products. The executive team is headed by Dr. Kenneth Hillan, who has held research and product development leadership roles during his career at Genentech for multiple products, including Rituxan® and Lucentis®.

Plazomicin

Our most advanced product candidate is plazomicin, a novel aminoglycoside designed by our scientists to overcome clinically relevant aminoglycoside resistance mechanisms. Aminoglycosides have been used successfully for the treatment of serious bacterial infections for more than 50 years. As a class, aminoglycosides have several important characteristics including rapid bactericidal activity, well-described pharmacokinetics, a lack of metabolism in humans, and excellent solubility and stability. However, the spread of resistance to currently marketed aminoglycosides has decreased their clinical utility. We developed plazomicin by chemically modifying an existing aminoglycoside, sisomicin, a natural product isolated from bacteria, to shield the regions of the molecule that are targeted by the enzymes responsible for aminoglycoside resistance. As a result of these modifications, plazomicin remains active against many MDR pathogens where most other major drug classes, including commercially available aminoglycosides such as gentamicin and amikacin, have limited activity. Based on this profile, we are developing plazomicin as an intravenous therapy for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including CRE, which the CDC considers to be one of the top three urgent resistance threats to public health.

We consider the following to be key attributes that support the clinical utility and commercial value of plazomicin:

- Potent activity in nonclinical studies against MDR Enterobacteriaceae, including CRE.
- Demonstration of comparable efficacy to levofloxacin, an approved antibiotic in the fluoroquinolone class, and of acceptable safety in a Phase 2 clinical trial in patients with complicated urinary tract infections caused primarily by non-MDR Enterobacteriaceae.
- Improved dosing strategy as compared to existing aminoglycosides, and individualized patient dosing using our *in vitro* assay, a clinical laboratory test conducted on blood samples to measure plazomicin concentrations.
- Potential to demonstrate a mortality benefit over currently available therapy in the treatment of life-threatening CRE infections.
- Potential to reduce the healthcare costs associated with the treatment of such infections.

Our pivotal Phase 3 trial is a pathogen-specific trial that will enroll patients with a high risk of mortality and, if successful, provide clinical evidence of the superiority of plazomicin versus the best currently available therapy for life-threatening bloodstream infections and pneumonia due to CRE. Unlike most antibiotic trials, which are designed to show non-inferiority to the current standard of care, our trial is a superiority trial with a primary efficacy endpoint of all-cause mortality at 28 days. Through the Special Protocol Assessment procedure, the FDA has agreed on the design and planned analyses of our pivotal Phase 3 trial. We expect to report top-line data from our Phase 3 trial in the first half of 2017, with interim analyses projected to occur in 2015 and 2016.

Table of Contents

Index to Financial Statements

We also intend to initiate a supportive efficacy trial in patients with serious CRE infections by the end of 2014, and we expect top-line data to be available in the fourth quarter of 2015. The FDA has granted us fast track designation for plazomicin for the treatment of serious and life-threatening CRE infections. We believe our planned development program, if successful, will also be acceptable to support a marketing application for plazomicin in the European Union.

We believe that plazomicin has the potential to become the new standard of care for the treatment of CRE, based on the attributes outlined above. We intend to achieve our pricing and reimbursement objectives through demonstration of a mortality benefit in CRE patients as well as pharmacoeconomic analyses that demonstrate significant cost savings to the healthcare system with the use of plazomicin. We plan to commercialize plazomicin with a targeted U.S. sales force to promote plazomicin to hospital-based healthcare professionals in resistance hotspots. In key markets outside of the United States, including Europe, Asia, and Latin America, we believe we can maximize the value of plazomicin through licensing full product rights to one or more commercialization partners who have local market expertise.

Our Antibacterial Discovery and Development Engine

Since we commenced operations in 2004, we have focused on the discovery and development of antibiotics, including plazomicin, to treat gram-negative infections. Through our work on multiple antibiotic classes, we have developed proprietary know-how about the relationship between chemical structure and potency against gram-negative organisms. Our progress in discovering and developing gram-negative product candidates has been achieved through:

Knowledge of gram-negative antibiotic chemistry. We are able to engineer the chemical structure of molecules to avoid resistance mechanisms and to penetrate the double membranes of gram-negative pathogens.

Specialized compound libraries. Our chemistry libraries are designed to contain compounds that have the necessary properties for penetration of gram-negative bacteria and are used in screening campaigns against clinical isolates of MDR gram-negative pathogens.

Microbiology capabilities in clinically important pathogens. Our microbiological and molecular genetic expertise with key gram-negative pathogens allows us to rapidly validate new antibacterial targets, determine the mode of action of our new agents, and progress promising molecules to advanced testing.

Use of nonclinical data to predict clinical outcomes. We leverage animal data and computational modeling techniques to predict the clinical efficacy of our early developmental candidates.

Collaborations with industry-leading advisors and scientific experts. We have established relationships with advisors who include experts in antibacterial drug development and academic researchers in the field of antibiotic pharmacology.

Table of Contents

Index to Financial Statements

Research and Development Pipeline

In addition to plazomicin, our research and development pipeline includes two programs that specifically target infections caused by *Pseudomonas aeruginosa*, which we refer to as our antipseudomonal programs. The first is a program to discover and develop small molecule inhibitors of LpxC, which is an enzyme essential for the synthesis of the outer membrane of gram-negative bacteria, and the second is a therapeutic antibody program. We are also pursuing small molecule research programs targeting other essential gram-negative enzymes. The following table summarizes the status of plazomicin and our other research programs:

Our Strategy

Our strategy is to discover, develop, and commercialize new antibacterials for the treatment of gram-negative bacterial infections. Key elements of our strategy are as follows:

Complete our pivotal Phase 3 superiority trial of plazomicin in the treatment of CRE infections and obtain regulatory approval in both the United States and the European Union.

Demonstrate improved clinical benefit and pharmacoeconomic advantages of our product candidates over existing therapies.

Commercialize our products directly, either alone or with support from a commercialization partner, in the United States and through commercialization partners elsewhere.

Establish and leverage collaborations with non-commercial organizations for scientific expertise and funding support.

Build a portfolio of differentiated products for the treatment of MDR gram-negative infections.

Table of Contents

Index to Financial Statements

Risks Related to Our Business

Our ability to implement our current business strategy is subject to numerous risks, including those described in the section entitled Risk Factors immediately following this prospectus summary. These risks include, among others:

- 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.
- We are substantially dependent on the success of our lead product candidate, plazomicin.
- Our pivotal Phase 3 superiority 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.
- We may not be able to obtain regulatory approval for plazomicin or any other product candidate, or for our *in vitro* assay for plazomicin.
- We will need substantial additional funding.
- Even if plazomicin, or any other product candidate, obtains regulatory approval, it may not achieve the level of market acceptance by physicians, patients, hospitals, third-party payors, and others in the medical community necessary for commercial success.
- We may not be able to obtain adequate coverage and reimbursement from government and other third-party payors for plazomicin.
- Our use of government funding adds uncertainty to our research and commercialization efforts and subjects us to additional requirements and costs.
- If our intellectual property for plazomicin or any future product candidates is not adequate, we may not be able to compete effectively.

Corporate Information

We were incorporated in Delaware in 2002 and commenced operations in 2004. Our principal executive offices are located at 7000 Shoreline Court, Suite 371, South San Francisco, California 94080, and our telephone number is (650) 800-3636. Our website address is http://www.achaogen.com. The information contained in, or that can be accessed through, our website is not part of this prospectus.

Achaogen and the Achaogen logo are our trademarks. Each of the other trademarks, trade names, or service marks appearing in this prospectus belongs to its respective holder.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced

reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;

Table of Contents

Index to Financial Statements

reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration 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 may use these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenues exceed $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Table of Contents

Index to Financial Statements

The Offering

Common stock offered by us	6,000,000 shares
Common stock to be outstanding after this offering	16,780,647 shares
Option to purchase additional shares	The underwriters have a 30-day option to purchase a maximum of 900,000 additional shares of common stock to cover over-allotments, if any.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $63.5 million, or approximately $73.6 million if the underwriters exercise their option to purchase additional shares of common stock in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use approximately $35 million to $40 million of the net proceeds from this offering, in combination with the expected funding from our BARDA contract, to support our planned registration program for plazomicin and any remaining proceeds to fund our other research and development activities, and for working capital and general corporate expenditures, which may include scheduled repayments of our outstanding loan. See Use of Proceeds beginning on page 55.
Risk factors	See Risk Factors beginning on page 11 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
NASDAQ Global Market symbol	AKAO

The number of shares of common stock to be outstanding after this offering is based on 10,780,647 shares of common stock outstanding as of January 31, 2014 and excludes the following:

- 1,638,544 shares of common stock issuable upon exercise of stock options outstanding as of January 31, 2014 under our Amended and Restated 2003 Stock Plan, at a weighted-average exercise price of $6.19 per share;
- 121,555 shares of common stock reserved for issuance pursuant to future awards under our Amended and Restated 2003 Stock Plan as of January 31, 2014 that became available for issuance under our 2014 Equity Incentive Award Plan upon the effectiveness of the registration statement to which this prospectus relates;

963,636 additional shares of common stock reserved for issuance pursuant to future awards under our 2014 Equity Incentive Award Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which became effective upon the effectiveness of the registration statement to which this prospectus relates, of which options to purchase 187,909 shares of common stock at an exercise price equal to the initial public offering price set forth on the cover of this prospectus were granted coincident with this offering;

Table of Contents

Index to Financial Statements

145,454 shares of common stock reserved for future issuance under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and

40,454 shares of common stock issuable upon the exercise of warrants outstanding as of January 31, 2014 to purchase convertible preferred stock, assuming their conversion into warrants to purchase common stock immediately prior to the completion of this offering, at a weighted-average exercise price of $12.36 per share, which warrants are expected to remain outstanding following the completion of this offering.

Except as otherwise indicated, all information in this prospectus:

reflects the conversion immediately prior to the completion of this offering of all of our outstanding shares of convertible preferred stock into an aggregate of 10,386,894 shares of common stock;

reflects a 1-for-11 reverse stock split of our capital stock that was effected on March 10, 2014;

assumes the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering; and

assumes that the underwriters do not exercise their option to purchase additional shares of common stock.

Table of Contents

Index to Financial Statements

Summary Consolidated Financial Data

The following summary consolidated financial data for the years ended December 31, 2012 and 2013 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. You should read this data together with our consolidated financial statements and related notes appearing elsewhere in this prospectus and the information under the captions Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations. Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,	
	2012	2013
	(in thousands, except share and per share amounts)	
Consolidated Statement of Operations Data:		
Contract revenue	$ 17,941	$ 18,512
Operating expenses:		
Research and development	26,581	23,484
General and administrative	7,349	6,992
Total operating expenses	33,930	30,476
Loss from operations	(15,989)	(11,964)
Interest expense and other, net	(2,427)	(1,341)
Interest income and other, net	51	193
Net loss	$ (18,365)	$ (13,112)
Net loss per common share, basic and diluted(1)	$ (52.77)	$ (33.83)
Shares used to compute net loss per common share, basic and diluted(1)	347,993	387,547
Pro forma net loss per common share, basic and diluted(1)		$ (1.36)

(1) See Note 2 to our audited financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share and pro forma net loss per common share.

The table below presents our consolidated balance sheet data as of December 31, 2013:

on an actual basis;

on a pro forma basis to give effect to:

the conversion immediately prior to the completion of this offering of all of our outstanding shares of convertible preferred stock into an aggregate of 10,386,894 shares of common stock;

the exercise of a common stock warrant for 909 shares at an exercise price of $1.54 per share in January 2014, which shares are excluded from the number of shares outstanding as of December 31, 2013 on an actual basis;

the reclassification to additional paid-in capital of our convertible preferred stock warrant liabilities included in other long-term liabilities in connection with the conversion of our outstanding convertible preferred stock warrants into common stock warrants immediately prior to the completion of this offering; and

Table of Contents

Index to Financial Statements

the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering; and

on a pro forma as adjusted basis to give further effect to the sale of 6,000,000 shares of common stock in this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	As of December 31, 2013		
	Actual	Pro Forma	Pro Forma As Adjusted
		(unaudited)	
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 10,738	$ 10,738	$ 75,093
Working capital	8,852	8,852	72,395
Total assets	20,758	20,758	84,301
Notes payable	6,687	6,687	6,687
Other long-term liabilities	244		
Convertible preferred stock	132,278		
Accumulated deficit	(128,724)	(128,724)	(128,724)
Total stockholders (deficit) equity	(124,576)	7,946	71,489

Table of Contents

Index to Financial Statements

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding to invest in our common stock, you should carefully consider each of the following risk factors and all other information set forth in this prospectus and any related free writing prospectus. The following risks and the risks described elsewhere in this prospectus, including in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations, could materially harm our business, financial condition, operating results, cash flow and prospects. If that occurs, the trading price of our common stock could decline, and you may lose all or part of your investment.

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, 2012 and 2013, we derived all of our revenue from government contracts for research and development. Our net losses for the years ended December 31, 2012 and 2013 were $18.4 million and $13.1 million, respectively. As of December 31, 2013, we had an accumulated deficit of $128.7 million.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we conduct our pivotal Phase 3 superiority trial of our lead product candidate, 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 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.

Table of Contents

Index to Financial Statements

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 the first quarter of 2014, we initiated a pivotal Phase 3 superiority trial to evaluate the efficacy and safety of plazomicin in treating patients with serious gram-negative bacterial infections due to carbapenem-resistant Enterobacteriaceae, or CRE. We have not 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 complicated urinary tract infections, or cUTI. 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 Phase 3 trial or other clinical trials, which will depend substantially upon the satisfactory performance of third-party contractors;
- successful achievement of the objectives of our Phase 3 trial for plazomicin, including the demonstration of a mortality benefit, pharmacoeconomic benefits and a favorable risk-benefit outcome;
- receipt of marketing approvals from the U.S. Food and Drug Administration, or 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* assay, which must itself be approved or cleared for marketing by the FDA and certain other foreign regulatory agencies before we may commercialize plazomicin in the associated markets. If we are unable to develop or receive marketing approval for plazomicin or the *in vitro* assay in a timely manner or at all, we could experience significant delays or an inability to commercialize plazomicin, 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 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 trial 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

Table of Contents

Index to Financial Statements

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.

Although we initiated our pivotal Phase 3 superiority trial for plazomicin in the first quarter of 2014, we cannot be certain that the 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;
- to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and 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, or IRB, approval at each site;
- to recruit suitable patients to participate in a trial;
- 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; or
- to manufacture sufficient quantities of product candidate for use in clinical trials.

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. Although we will continue to look for opportunities for faster regulatory approval of plazomicin or our other product candidates, including potential additional clinical trials, we cannot guarantee that such opportunities will arise, that the FDA or other regulatory authorities will agree with any proposals we make or that such proposals, even if approved, will be successful.

We could also encounter delays if a clinical trial is suspended or terminated by us upon recommendation of the data monitoring committee for such trial, by the IRBs of the institutions in which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory

requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

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

Table of Contents

Index to Financial Statements

Our pivotal Phase 3 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 pivotal Phase 3 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 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 trial 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 trial.

Because our pivotal Phase 3 trial for plazomicin is enrolling patients with rare infections, finding a sufficient number of suitable patients with CRE infections to enroll in the trial will be a potential 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. 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.

Our Phase 3 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 trial will use a superiority design rather than a non-inferiority design. In order to meet our primary endpoint, we must show that plazomicin is superior to the comparator therapy with respect to all-cause mortality at 28 days. 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 trial. Our choice of a mortality endpoint means that success will depend to a significant degree on the accuracy of our assumptions about mortality rates in the comparator and plazomicin arms of our Phase 3 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 mortality than we expect, we may find that our trial is unfeasible or may have to enroll more patients at additional cost and delay.

Any failure to meet our endpoints in the Phase 3 trial or adequately address safety concerns would jeopardize our ability to obtain regulatory approval for and commercialize plazomicin 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*.

Table of Contents

Index to Financial Statements

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, or 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 a New Drug Application, or 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, our revenue will be dependent, in part, upon our or a commercial partner s ability to obtain regulatory approval of an *in vitro* assay to be used with plazomicin, as well as upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency that plazomicin is safe and effective for the requested indication;
- the FDA s or the applicable foreign regulatory agency s disagreement with the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of plazomicin outweigh any safety or other perceived risks;
- the FDA s or the applicable foreign regulatory agency s requirement for additional preclinical or clinical studies;
- the FDA s or the applicable foreign regulatory agency s non-approval of the formulation, labeling or the specifications of plazomicin;
- the FDA s or the applicable foreign regulatory agency s failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- 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.

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. 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.

Table of Contents

Index to Financial Statements

Although we have entered into a Special Protocol Assessment agreement with the FDA relating to our pivotal Phase 3 superiority trial of plazomicin, and have obtained feedback from the EMA through their scientific advice procedure, this agreement and feedback do not guarantee any particular outcome with respect to regulatory review of the pivotal trial or with respect to regulatory approval of plazomicin.

In September 2013, the protocol for our pivotal Phase 3 superiority trial of plazomicin was reviewed and agreed upon by the FDA under a Special Protocol Assessment agreement, or SPA, which creates a written agreement between the sponsoring company and the FDA regarding clinical trial design and other clinical trial issues, such as the trial endpoints, that can be used to support approval of a product candidate. The SPA is intended to provide assurance that if the agreed upon clinical trial protocols are followed and the clinical trial endpoints are achieved, the data may serve as the primary basis for an efficacy claim in support of an NDA. Agreement on an SPA is not a guarantee of approval, and there is no assurance that the design of, or data collected from, the trial will be adequate to obtain the requisite regulatory approval. The SPA is not binding on the FDA if public health concerns unrecognized at the time the SPA was entered into become evident, if other new scientific concerns regarding product safety or efficacy arise, if the information provided by the sponsoring company in the SPA request changes or is found to be false or misleading or omit relevant facts, or if the sponsoring company fails to comply with the agreed upon clinical trial protocols. Moreover, SPA agreements do not address all of the variables and details that may go into planning for or conducting a clinical trial, and any change in the protocol for a clinical trial can invalidate the SPA agreement. In addition, upon written agreement of both parties, the SPA may be changed, and the FDA retains significant latitude and discretion in interpreting the terms of an SPA and any resulting trial data. As a result, we do not know how the FDA will interpret the parties respective commitments under the SPA, how it will interpret the data and results from the pivotal Phase 3 superiority trial, whether the FDA will require that we conduct or complete one or more additional clinical trials to support potential approval, including the completion of our ongoing clinical trial of plazomicin, or whether plazomicin will receive any regulatory approvals.

Similarly, we have solicited feedback on our planned development program for plazomicin through the EMA s scientific advice procedure and believe that our program, if successful, will be acceptable to support a marketing application in the European Union, or EU. However, this feedback is not a guarantee of approval, and we do not know how the EMA will interpret the data and results from our Phase 3 trial and other elements of our development program, whether they will require that we conduct one or more additional clinical trials or nonclinical studies to support potential approval, or whether plazomicin will receive any regulatory approvals in the EU.

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.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, an institutional review board, 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 complicated urinary tract infections, and there have been no

Table of Contents

Index to Financial Statements

reports of serious adverse events related to plazomicin in our completed clinical trials. However, our planned pivotal Phase 3 superiority trial for plazomicin will involve more extended dosing (7 14 days) 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 when bacteria may evolve resistance to plazomicin, 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. We cannot predict when bacterial resistance to plazomicin may become prevalent.

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 is currently rare outside of certain countries in Asia, there have been isolated cases of infections by bacteria carrying ribosomal methyltransferase elsewhere, including 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.

Failure to successfully validate, develop and obtain regulatory clearance or approval for our in vitro assay could harm our product development strategy.

An important element of our clinical development strategy for plazomicin is the development of an *in vitro* assay to measure levels of plazomicin in the blood, which will enable patients to receive safe and efficacious

Table of Contents

Index to Financial Statements

doses of plazomicin. In collaboration with ARK Diagnostics, Inc., or ARK, we are co-developing such an assay, which will be utilized during our pivotal Phase 3 superiority trial as well as in connection with the commercialization of plazomicin, if approved.

In vitro diagnostic 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 *in vitro* diagnostic 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, a companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic. If the regulatory clearance or approval process for our diagnostic assay is delayed, our ability to commercialize plazomicin could be delayed until we receive regulatory clearance or approval for the companion diagnostic.

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, ARK or our future collaborators may encounter difficulties in developing, obtaining regulatory approval for and manufacturing assays similar to those we face with respect to our drug product candidates themselves, including issues with achieving regulatory clearance or approval, or producing sufficient quantities of the assay with appropriate quality standards. 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.

We will be dependent on ARK to develop and manufacture our in vitro assay for our pivotal Phase 3 superiority trial for plazomicin, and may become dependent on ARK to commercialize such in vitro assay.

We will be dependent on the sustained cooperation and effort of ARK in the development and manufacture of our *in vitro* assay for plazomicin for our pivotal Phase 3 superiority trial, 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 *in vitro* 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 U.S. 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, clinical trials required to support approval of our product candidates 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 U.S. 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

Table of Contents

Index to Financial Statements

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.

Our recurring losses from operations and negative cash flows have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of, and for the year ended, December 31, 2013. Our only current source of revenue is for services performed for the development of our product candidates under government contracts, and we do not expect to generate revenue from product sales until, and unless, we receive regulatory approval of and successfully commercialize plazomicin. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

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 conduct our pivotal Phase 3 superiority trial 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 December 31, 2013, we had working capital of $8.9 million and cash and cash equivalents of $10.7 million. Assuming we receive the full amount of allocated funding under our contract with the Biomedical Advanced Research and Development Authority, or BARDA, together with the proceeds from this offering, we expect such funds will be sufficient to fund our Phase 3 trial of plazomicin through receipt of top-line data. However, our operating plan may change as a result of factors currently unknown to us, and we may need to seek additional funds sooner than planned. 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 or strategic collaborations. Additional financing may not be available to us when we need it or it may not be available to us on favorable 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. Our future financing requirements will depend on many factors, some of which are beyond our control, including:

- continued funding under our contract with BARDA;
- the size and type of the nonclinical and clinical trials that we decide to pursue in the development of our product candidates, including plazomicin;
- the type, number, costs and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- the rate of progress and cost of 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;

Table of Contents

Index to Financial Statements

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;

the amount of funds we receive in this offering; 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.

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 will focus on our pivotal Phase 3 superiority trial 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;

Table of Contents

Index to Financial Statements

a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors; and

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

We 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. Although we are exploring reformulations and prodrugs of ACHN-975 to address the issue, we cannot guarantee that these efforts will be successful or that any alternative backup compounds we turn to will avoid the issue or otherwise prove to be viable product candidates. We would have to submit a new Investigational New Drug application for any modified or backup compound we seek to advance to clinical trials, which would incur further delay.

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 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;

Table of Contents

Index to Financial Statements

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-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 *in vitro* 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, or MS-DRGs. 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. We intend to seek pricing and reimbursement for plazomicin based on the superior mortality benefit and pharmacoeconomic advantages over existing treatments we will seek to demonstrate in our Phase 3 trial. If we are unable to demonstrate such benefits, or if governmental or other third-party payors do not view the benefits 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

Table of Contents

Index to Financial Statements

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, or 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, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

We rely on third-party contract manufacturing organizations to manufacture and supply plazomicin 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

Table of Contents

Index to Financial Statements

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;
- 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.

Table of Contents

Index to Financial Statements

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 in vitro 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 *in vitro* 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 *in vitro* assay. If we are unable to effectively establish and manage the distribution process, the commercial launch and sales of plazomicin and the associated *in vitro* 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 *in vitro* 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 *in vitro* assay, or complaints regarding them;
- not effectively sell or support plazomicin or the associated *in vitro* assay with sufficient cold storage;
- reduce their efforts or discontinue to sell or support plazomicin or the *in vitro* assay;
- not devote the resources necessary to sell plazomicin or the *in vitro* 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 *in vitro* 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.

25

Table of Contents

Index to Financial Statements

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 multi-drug resistant infections that we would expect would compete with plazomicin, including 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 clinical development by third parties to treat multi-drug resistant infections. Forest Laboratories and AstraZeneca are developing ceftazidime/avibactam and ceftaroline/avibactam for pneumonia and complicated urinary and intra-abdominal infections. Tetraphase Pharmaceuticals is developing eravacycline for complicated urinary and intra-abdominal infections. The Medicines Company is developing Carbavance for complicated urinary tract infections and MDR gram-negative infections, including CRE. We may also eventually face competition from products currently in the research or preclinical 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, or 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.

Table of Contents

Index to Financial Statements

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.

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.

Table of Contents

Index to Financial Statements

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

As of December 31, 2013, we had $6.7 million of indebtedness outstanding under our loan and security agreement with Silicon Valley Bank and Oxford Finance LLC. The loan agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, or to redeem capital stock. Our business may be adversely affected by these restrictions on our ability to operate our business.

Additionally, we may be required to repay the outstanding indebtedness under the loan facility if an event of default occurs under the loan agreement. Under the loan agreement, an event of default will occur if, among other things, we fail to make payments under the loan agreement; we breach any of our covenants under the loan agreement, subject to specified cure periods with respect to certain breaches; a lender determines in good faith that we are unable to satisfy our obligations under the loan agreement as they become due and that our principal investors do not intend to fund amounts necessary to satisfy such obligations; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit the holder of indebtedness to accelerate the maturity of such indebtedness or that could have a material adverse change on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others, rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Oxford Finance LLC could also exercise its rights as collateral agent to take possession of and to dispose the collateral of the loan for the benefit of the lenders, which collateral includes all of our property other than our intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

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

As of December 31, 2013, we had 39 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, commercialize plazomicin or other product candidates and transition to becoming a public reporting company. 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 pivotal Phase 3 superiority trial, which is 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.

Table of Contents

Index to Financial Statements

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 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.

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

Table of Contents

Index to Financial Statements

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.

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.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

Prior to this offering, we have not been subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the other rules and regulations of the SEC or any securities exchange relating to public companies. We are working with our legal, independent accounting and financial advisors 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 that will be required in order to adequately prepare for 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 will also 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, being a public company could make it more difficult or more costly for us to obtain certain types of insurance, including directors and officers liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events 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.

Table of Contents

Index to Financial Statements

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 the reports required by these rules. We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or The NASDAQ Stock Market LLC, or NASDAQ. Any such action could adversely affect our financial results or investors confidence in us and could cause our stock price to fall. Moreover, 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 NASDAQ, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources and could materially adversely affect our stock price. Deficient internal controls could also cause us to fail to meet our reporting obligations or cause investors to lose confidence in our reported financial information, which could have a negative effect on our stock price.

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

Upon completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We 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;

Table of Contents

Index to Financial Statements

differing United States 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.

Risks Related to Our United States 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 the U.S. Department of Defense s Defense Threat Reduction Agency, or DTRA, and from the National Institute of Health s National Institute of Allergy and Infectious Diseases, or NIAID, 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;

Table of Contents

Index to Financial Statements

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, or 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 United States 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, 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 pivotal Phase 3 superiority trial of plazomicin, and if we do not receive all of the funds under this contract, we may be forced to suspend or terminate this program or obtain alternative sources of funding.

We expect a significant portion of the funding for our pivotal Phase 3 superiority trial of plazomicin to come from our BARDA contract. 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 intend to use a portion of the proceeds from this offering to fund our plazomicin development program, any reduction or delay in BARDA funding may force us to suspend or terminate the

Table of Contents

Index to Financial Statements

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, among other things, our planned additional safety trial of plazomicin, 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.

United States 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 United States government s determination to award a future contract or contract option may be challenged by an interested party, such as another bidder, at the United States Government Accountability Office, or 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 United States 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, or DHHS, the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors. These agencies

34

Table of Contents

Index to Financial Statements

review a contractor s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

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

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

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease.

There is no assurance that we will receive payment from DTRA for additional expenses related to our LpxC inhibitor program, and the audit being conducted in connection with our proposal for such payments may require us to refund a portion of past payments.

In November 2012, DTRA terminated for convenience a contract with us that provided funding for our LpxC inhibitor program. In connection with the termination, we are seeking payment from DTRA for additional expenses we have incurred. We cannot be certain that we will be able to prevail upon DTRA to make such payments or that we would be successful in any subsequent legal proceeding to challenge DTRA s decision.

In connection with our claim for payment from DTRA, we are undergoing an audit by the DCAA of the expenses for which we are seeking payment, as well as of $33.5 million previously paid to us under the DTRA contract. The results of the audit may lead certain expenses to be disallowed under the contract, which may reduce the size of any payment we may receive from DTRA, or may require us to refund some of the previously paid amounts we received from DTRA, which would adversely affect our financial position and results of operations.

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, or 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.

Table of Contents

Index to Financial Statements

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

Risks Related to Intellectual Property

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

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

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

Furthermore, certain of the patents that we license from the University of Washington are co-owned by Novartis. 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, including ACHN-975. 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

Table of Contents

Index to Financial Statements

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

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

Table of Contents

Index to Financial Statements

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.

Table of Contents

Index to Financial Statements

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

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

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

While the primary patent family covering plazomicin is Achaogen-owned, our development and commercialization of plazomicin is subject to our license agreement with Isis Pharmaceuticals, Inc., and a portion of the patent portfolio for our LpxC inhibitor program, including ACHN-975, 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, including ACHN-975.

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;

Table of Contents

Index to Financial Statements

others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

pending patent applications that we own or license may not lead to issued patents;

issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

we may not develop or in-license additional proprietary technologies that are patentable; and

the patents of others may have an adverse effect on our business.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

Provisions in our United States 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, or 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

Table of Contents

Index to Financial Statements

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.

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

Table of Contents

Index to Financial Statements

we nor any future collaboration partner is permitted to market plazomicin or any other product candidate in the United States until we receive regulatory approval of an NDA from the FDA.

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

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

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

The regulatory approval process is expensive and may take several years to complete. The FDA and foreign regulatory entities have substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that

cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

product candidate may not be deemed safe or effective;

Table of Contents

Index to Financial Statements

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;

Table of Contents

Index to Financial Statements

mandated modifications to promotional materials or the required provision of corrective information to healthcare practitioners;

restrictions imposed on the product or its manufacturers or manufacturing processes;

restrictions imposed on the labeling or marketing of the product;

restrictions imposed on product distribution or use;

requirements for post-marketing clinical trials;

suspension of any ongoing clinical trials;

suspension of or withdrawal of regulatory approval;

voluntary or mandatory product recalls and publicity requirements;

refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;

restrictions on operations, including costly new manufacturing requirements;

seizure or detention of our products;

refusal to permit the import or export of our products;

required entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

civil or criminal penalties; or

injunctions.

Widely publicized events concerning the safety risk of certain drug products have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the imposition by the FDA of risk evaluation and mitigation strategies, or 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, or 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, or 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 European Medicines

Table of Contents

Index to Financial Statements

Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as for drugs produced through certain specified biotechnological processes (such as recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, and hybridoma and monoclonal antibody methods), advanced therapy medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

national MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

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

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

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

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which is intended to contain or reduce the costs of medical products and services. For example, in March 2010, the President signed one of the most significant healthcare reform measures in decades, the Affordable Care Act. 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%;

Table of Contents

Index to Financial Statements

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, or the ATRA, 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;

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;

Table of Contents

Index to Financial Statements

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 and This Offering

The price of our common stock may be volatile, and you may not be able to resell your shares at or above the initial public offering price.

The initial public offering price for the shares of our common stock sold in this offering has been determined by negotiation between the underwriters and us. This price may not reflect the market price of our common stock following this offering. You may be unable to sell your shares of common stock at or above the initial public offering price due to fluctuations 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:

ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;

announcements relating to our Phase 3 trial for plazomicin, including any periodic updates relating to enrollment of trial subjects, adverse events, site initiation, and timing of release of interim analyses and final trial results;

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

Table of Contents

Index to Financial Statements

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 have 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 January 31, 2014 (including options exercisable within 60 days of January 31, 2014), after this offering, assuming no exercise of the underwriters option to purchase additional shares of common stock, our officers and directors, together with holders of 5% or more of our outstanding common stock before this offering and their respective affiliates, will beneficially own

Table of Contents

Index to Financial Statements

approximately 59.1% 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 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 shareholder 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 of 1933, as amended, or 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 are choosing 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.

Future sales 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. Based on the number of shares of common stock outstanding as of January 31, 2014, upon the completion of this offering, we will have outstanding a total of 16,780,647 shares of common stock, assuming no exercise of the underwriters option to purchase additional shares of common stock. Of these shares, only the shares of common stock sold by us in this offering, plus any shares sold upon exercise of the underwriters option to purchase additional shares of common stock, will be freely tradable without restriction, unless held by our affiliates, in the public market immediately following this offering.

We expect that the lock-up agreements with the underwriters pertaining to this offering will expire 180 days from the date of this prospectus. After the lock-up agreements expire, up to an additional 10,780,647 shares of common stock will be eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, with respect to shares held by directors, executive officers and other affiliates. The underwriters may, however, in their sole discretion, permit our officers, directors

Table of Contents

Index to Financial Statements

and other stockholders and the holders of our outstanding options and warrants who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements. Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline.

In addition, based on the number of shares subject to outstanding awards under our Amended and Restated 2003 Stock Plan, or 2003 Plan, or available for issuance thereunder, as of January 31, 2014, and including the initial reserves under our 2014 Equity Incentive Award Plan, or 2014 Plan, and our Employee Stock Purchase Plan, or ESPP, 2,869,189 shares of common stock that are either subject to outstanding options, outstanding but subject to vesting, or reserved for future issuance under the 2003 Plan, 2014 Plan, or ESPP will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. We also plan to file 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, subject to the lock-up agreements, applicable vesting schedules and, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 for shares. The 2014 Plan also contains a provision for the annual increase of the number of shares reserved for issuance under such plan, as described elsewhere in this prospectus, which shares we also intend to register. If the shares we may issue from time to time under the 2003 Plan, 2014 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.

Certain holders of 10,374,133 shares of our common stock, warrants to purchase our capital stock and the 40,454 shares of common stock issuable upon exercise of those warrants will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. See Description of Capital Stock Registration Rights. 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.

If there is no viable public market for our common stock, you may not be able to sell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for our common stock, and there can be no assurance that a regular trading market will develop and continue after this offering or that the market price of our common stock will not decline below the initial public offering price. The initial public offering price was determined through negotiations between us and the underwriters and may not be indicative of the market price of our common stock following this offering. Among the factors considered in such negotiations were prevailing market conditions, certain of our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant. See Underwriting for additional information.

Investors in this offering will suffer immediate and substantial dilution of their investment.

If you purchase common stock in this offering, you will pay more for your shares than our pro forma as adjusted net tangible book value per share. Based upon the initial public offering price of $12.00 per share, you will incur immediate and substantial dilution of $7.74 per share, representing the difference between the initial public offering price and our pro forma as adjusted net tangible book value per share. Based upon the initial public offering price, purchasers of common stock in this offering will have contributed approximately 36.0% of the aggregate purchase price paid by all purchasers of our stock but will own only approximately 35.8% of our common stock outstanding after this offering.

We have also issued warrants and options in the past to acquire common stock at prices significantly below the initial offering price. As of January 31, 2014, there were 39,114 shares of convertible preferred stock subject to outstanding warrants with a weighted-average exercise price of $12.78 per share (such warrants would be converted into warrants for 40,454 shares of common stock with a weighted-average exercise price of $12.36 as a

Table of Contents

Index to Financial Statements

result of this offering) and 1,638,544 shares of common stock subject to outstanding options with a weighted-average exercise price of $6.19 per share. To the extent that these outstanding warrants and options are ultimately exercised, you will incur further dilution, and our stock price may decline.

Raising additional capital may cause dilution to our existing stockholders or involve the issuance of securities with rights, preferences and privileges senior to those of holders of our common stock.

To raise capital, we may from time to time issue additional shares of common stock at a discount from the then-current trading price of our common stock. As a result, our common stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. Whether or not we issue additional shares of common stock at a discount, any issuance of common stock will, and any issuance of other equity securities or of options, warrants or other rights to purchase common stock may, result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to decline. New investors could also gain rights, preferences and privileges senior to those of holders of our common stock, which could cause the price of our common stock to decline.

We will have broad discretion in the use of the net proceeds of this offering and may not use them effectively.

Our management will have broad discretion over the use of the net proceeds from this offering. Because of the number and variability of factors that will determine our use of such proceeds, you may not agree with how we allocate or spend the proceeds from this offering. We may pursue collaborations, clinical trials or discovery and development programs that do not result in an increase in the market value of our common shares and that may increase our losses. Our failure to allocate and spend the net proceeds from this offering effectively would have a material adverse effect on our financial condition and business. Until the net proceeds are used, they may be placed in investments that do not produce significant investment returns or that may lose value.

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 amended and restated certificate of incorporation and our amended and restated bylaws that will become effective upon the closing of this offering 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;

Table of Contents

Index to Financial Statements

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.

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. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, 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.

Table of Contents

Index to Financial Statements

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, could, will, would, should, expect, plan, anticipate, believe, estimate, intend, predict, seek, contemplate, po negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the timing of initiation, enrollment and completion of our pivotal Phase 3 superiority trial for plazomicin, including our expectations regarding the timing of receipt and release of interim and full trial results;
- our expectations regarding the timing of submission of an NDA for plazomicin following our pivotal Phase 3 superiority trial;
- our expectations regarding the receipt of approvals to market plazomicin;
- our expectations regarding the pricing, reimbursement and commercial potential of plazomicin and our other product candidates;
- our expectations regarding our ability to validate, develop, and obtain regulatory approval for our *in vitro* assay to measure plazomicin levels;
- the initiation, timing, progress and results of any preclinical studies and clinical trials we may initiate;
- our ability to discover and develop additional product candidates and advance such product candidates through preclinical and clinical studies;
- our future research and development programs;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals or of alternative regulatory pathways for any of our product candidates;

our ability to establish collaborations or obtain additional government funding or receive funding under existing contracts;

our use of proceeds from this offering;

our financial performance; and

developments relating to our competitors and our industry.

Any forward-looking statements in this prospectus reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Risk Factors and elsewhere in this prospectus. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Table of Contents

Index to Financial Statements

This prospectus also contains estimates, projections and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, the incidence of certain medical conditions, statements that certain drugs, classes of drugs or dosages are the most widely prescribed in the United States or other markets, the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, prescriber and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Table of Contents

Index to Financial Statements

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 6,000,000 shares of our common stock in this offering will be approximately $63.5 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds from this offering will be approximately $73.6 million after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We plan to use approximately $35 million to $40 million of the net proceeds from this offering in combination with the expected funding from our BARDA contract, to support our planned registration program for plazomicin. We plan to use the remainder to fund our other research and development activities, and for working capital and general corporate expenditures. We may use a portion of the proceeds to make scheduled payments of principal and interest on our outstanding loan with Oxford Finance LLC and Silicon Valley Bank, which is scheduled to be fully repaid by February 2015. For additional information related to our outstanding loan, including the interest rate and maturity, see Management s Discussion and Analysis of Financial Condition and Results of Operations Contrctual Obligations and Commitments Notes Payable.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions. Assuming we receive the full amount of funding from our BARDA contract, including under the unexercised option, we expect such funds, together with the proceeds from this offering, will be sufficient to fund our development of plazomicin through receipt of top-line data from our Phase 3 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. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the timing and speed of enrollment of our pivotal Phase 3 superiority trial of plazomicin, the status of our research and development programs, the continued receipt of funding under our contract with BARDA, and whether regulatory authorities require us to perform additional clinical trials of plazomicin in order to obtain marketing approvals. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We may find it necessary or advisable to use the net proceeds from this offering for other purposes, and we will have broad discretion in the application of net proceeds.

Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

Table of Contents

Index to Financial Statements

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors. In addition, unless waived, the terms of our loan from Silicon Valley Bank and Oxford Finance prohibit us from paying any cash dividends.

Table of Contents

Index to Financial Statements

CAPITALIZATION

The following table sets forth our cash, cash equivalents and capitalization as of December 31, 2013:

- on an actual basis;
- on a pro forma basis to give effect to:
  - the conversion immediately prior to the completion of this offering of all of our outstanding shares of convertible preferred stock into an aggregate of 10,386,894 shares of common stock;
  - the exercise of a common stock warrant for 909 shares at an exercise price of $1.54 per share in January 2014, which shares are excluded from the number of shares outstanding as of December 31, 2013 on an actual basis;
  - the reclassification to additional paid-in capital of our convertible preferred stock warrant liabilities included in other long-term liabilities in connection with the conversion of our outstanding convertible preferred stock warrants into common stock warrants, immediately prior to the completion of this offering; and
  - the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering.
- on a pro forma as adjusted basis to give further effect to the sale of 6,000,000 shares of common stock in this offering, after deducting the underwriting discount and commissions and estimated offering expenses payable by us.

Table of Contents

Index to Financial Statements

You should read this information together with our audited consolidated financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the heading Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations.

	As of December 31, 2013		
	Actual	Pro Forma	Pro Forma as Adjusted
		(unaudited)	
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 10,738	$ 10,738	$ 75,093
Notes payable	$ 6,687	$ 6,687	$ 6,687
Other long-term liabilities	244		
Convertible preferred stock, par value $0.001 per share: 132,202,910 shares authorized, 9,796,342 shares issued and outstanding, actual; no shares authorized, issued and outstanding pro forma and pro forma as adjusted	132,278		
Stockholders equity (deficit):			
Preferred stock, $0.001 par value per share: no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, par value $0.001 per share: 163,000,000 shares authorized, 392,844 shares issued and outstanding, actual; 290,000,000 shares authorized, 10,780,647 shares issued and outstanding pro forma; 16,780,647 shares issued and outstanding pro forma as adjusted		11	17
Additional paid-in capital	4,148	136,659	200,196
Accumulated deficit	(128,724)	(128,724)	(128,724)
Total stockholders equity (deficit)	(124,576)	7,946	71,489
Total capitalization	$ 14,633	$ 14,633	$ 78,176

The number of shares of common stock issued and outstanding actual, pro forma and pro forma as adjusted in the table above excludes the following shares as of December 31, 2013:

1,405,550 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013 under our Amended and Restated 2003 Stock Plan, at a weighted-average exercise price of $5.68 per share;

127,277 shares of common stock reserved for issuance as of December 31, 2013 pursuant to future awards under our Amended and Restated 2003 Stock Plan;

963,636 additional shares of common stock reserved for issuance pursuant to future awards under our 2014 Equity Incentive Award Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which became effective upon the effectiveness of the registration statement to which this prospectus relates, of which options to purchase 187,909 shares of common stock at an exercise price equal to the initial public offering price set forth on the cover of this prospectus were granted coincident with this offering;

145,454 shares of common stock reserved for future issuance under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and

Table of Contents

Index to Financial Statements

40,454 shares of common stock issuable upon the exercise of warrants outstanding to purchase convertible preferred stock, assuming their conversion into warrants to purchase common stock immediately prior to the completion of this offering, at a weighted-average exercise price of $12.36 per share, which warrants are expected to remain outstanding following the completion of this offering.

Table of Contents

Index to Financial Statements

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities and convertible preferred stock, by the number of shares of common stock outstanding. Our historical net tangible book value as of December 31, 2013 was $(125.4) million, or $(319.18) per share. Our pro forma net tangible book value as of December 31, 2013 was $7.1 million, or $0.66 per share. Pro forma net tangible book value per share, before the issuance and sale of shares in this offering, gives effect to:

- the conversion immediately prior to the completion of this offering of all of our outstanding shares of convertible preferred stock into an aggregate of 10,386,894 shares of common stock;
- the exercise of a common stock warrant for 909 shares at an exercise price of $1.54 per share in January 2014, which shares are excluded from the number of shares outstanding as of December 31, 2013 on an actual basis;
- the reclassification to additional paid-in capital of our convertible preferred stock warrant liabilities included in other long-term liabilities in connection with the conversion of our outstanding convertible preferred stock warrants into common stock warrants immediately prior to the completion of this offering; and
- the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after completion of this offering. After giving effect to our sale of 6,000,000 shares of common stock in this offering, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2013 would have been $71.5 million, or $4.26 per share. This represents an immediate increase in net tangible book value of $3.60 per share to existing stockholders and an immediate dilution in net tangible book value of $7.74 per share to purchasers of common stock in this offering, as illustrated in the following table:

Initial public offering price per share		$ 12.00
Historical net tangible book value per share as of December 31, 2013	$ (319.18)	
Pro forma change in net tangible book value per share attributable to pro forma transactions and other adjustments described above, as of December 31, 2013	319.84	
Pro forma net tangible book value per share as of December 31, 2013	0.66	
Increase in pro forma net tangible book value per share attributable to new investors	3.60	
Pro forma as adjusted net tangible book value per share after this offering		4.26
Dilution per share to investors participating in this offering		$ 7.74

If the underwriters option to purchase additional shares from us is exercised in full, the pro forma as adjusted net tangible book value per share after this offering would be $4.61 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be $0.35 per share and the dilution to new investors purchasing shares in this offering would be $7.39 per share.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise

Table of Contents

Index to Financial Statements

additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The following table presents, on the pro forma as adjusted basis described above, as of December 31, 2013, the differences between the existing stockholders and the purchasers of shares in this offering with respect to the number of shares purchased from us, the total consideration paid, which includes net proceeds received from the issuance of common and preferred stock, cash received from the exercise of stock options and warrants and the value of any stock issued for services and the average price paid per share (in thousands, except share and per share amounts and percentages):

	Shares Purchased		Total Consideration		Average Price per Share
	Number	Percent	Amount	Percent	
Existing stockholders	10,780,647	64.2%	$ 128,153	64.0%	$ 11.89
New investors	6,000,000	35.8	72,000	36.0	12.00
Totals	16,780,647	100%	$ 200,153	100%	$ 11.93

If the underwriters exercise their option to purchase additional shares of our common stock in full, our existing stockholders would own 61.0% and our new investors would own 39.0% of the total number of shares of our common stock outstanding upon completion of this offering. The total consideration paid by our existing stockholders would be approximately $128.2 million, or 60.7%, and the total consideration paid by our new investors would be $82.8 million, or 39.3%.

The information and tables in this section are based on shares of common stock outstanding as of December 31, 2013 and exclude the following:

- 1,405,550 shares of common stock issuable upon exercise of stock options outstanding under our Amended and Restated 2003 Stock Plan as of December 31, 2013, at a weighted-average exercise price of $5.68 per share;
- 127,277 shares of common stock reserved for issuance as of December 31, 2013 pursuant to future awards under our Amended and Restated 2003 Stock Plan;
- 963,636 additional shares of common stock reserved for issuance pursuant to future awards under our 2014 Equity Incentive Award Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which became effective upon the effectiveness of the registration statement to which this prospectus relates, of which options to purchase 187,909 shares of common stock at an exercise price equal to the initial public offering price set forth on the cover of this prospectus were granted coincident with this offering;
- 145,454 shares of common stock reserved for future issuance under our Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and
- 40,454 shares of common stock issuable upon the exercise of warrants outstanding as of December 31, 2013 to purchase convertible preferred stock, assuming their conversion into warrants to purchase common stock immediately prior to the completion of this offering, at a weighted-average exercise price of $12.36 per share, which warrants are expected to remain outstanding following the completion of this offering.

61

Table of Contents

Index to Financial Statements

SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated statement of operations data for the years ended December 31, 2012 and 2013 and the selected consolidated balance sheet data as of December 31, 2012 and 2013 are derived from our audited consolidated financial statements included elsewhere in this prospectus.

Our historical results are not necessarily indicative of the results that may be expected in the future and interim results are not necessarily indicative of results to be expected for the full year. You should read the selected historical consolidated financial data below in conjunction with the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2012	2013
	(in thousands, except share and per share amounts)	
Consolidated Statement of Operations Data:		
Contract revenue	$ 17,941	$ 18,512
Operating expenses:		
Research and development	26,581	23,484
General and administrative	7,349	6,992
Total operating expenses	33,930	30,476
Loss from operations	(15,989)	(11,964)
Interest expense and other, net	(2,427)	(1,341)
Interest income and other, net	51	193
Net loss	$ (18,365)	$ (13,112)
Net loss per common share, basic and diluted(1)	$ (52.77)	$ (33.83)
Shares used to compute net loss per common share, basic and diluted(1)	347,993	387,547
Pro forma net loss per common share, basic and diluted(1)		$ (1.36)

(1) See Note 2 to our audited financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share and pro forma net loss per common share.

	As of December 31,	
	2012	2013
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 7,073	$ 10,738
Working (deficit) capital	(306)	8,852
Total assets	13,266	20,758
Notes payable	10,847	6,687

Other long-term liabilities	237	244
Convertible preferred stock	100,354	132,278
Accumulated deficit	(115,612)	(128,724)
Total stockholders deficit	(112,578)	(124,576)

Table of Contents

Index to Financial Statements

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this prospectus entitled Selected Consolidated Financial Data and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions. As a result of many factors, including those factors set forth in the Risk Factors section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel antibacterials to treat multi-drug resistant, or MDR, gram-negative infections. We are developing plazomicin, our lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae, or CRE. In 2013, the Centers for Disease Control and Prevention identified CRE as a nightmare bacteria and an immediate public health threat that requires urgent and aggressive action. We initiated a Phase 3 superiority trial of plazomicin in the first quarter of 2014. Through the Special Protocol Assessment procedure, the U.S. Food and Drug Administration, or FDA, has agreed that the design and planned analyses of our single pivotal Phase 3 trial adequately address objectives in support of a New Drug Application. We have also received FDA fast track designation for the development and regulatory review of plazomicin to treat serious and life-threatening CRE infections. Our plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority for up to $103.8 million. We have global commercialization rights to plazomicin, which has patent protection in the United States extending through 2031. Plazomicin is the first clinical candidate from our gram-negative antibiotic discovery engine, and we have other programs in early and late preclinical stages focused on other MDR gram-negative infections.

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 MDR *Pseudomonas aeruginosa.* We are taking a multifaceted approach to identify new antipseudomonal agents through our small molecule program, or LpxC inhibitor program, and therapeutic antibody discovery program. We expect to nominate at least one clinical candidate from our antipseudomonal program in 2014 and to file an investigational new drug application, or IND, in 2015. We also maintain an active discovery and development program in infections caused by gram-negative bacteria, drawing on knowledge gained through our work on LpxC inhibitors to identify compounds that bind and inhibit additional essential enzymes in the gram-negative outer membrane biosynthesis pathway.

We have financed our operations primarily through private placements of our equity securities, funding under our contracts with government agencies and certain debt related financing arrangements. We have never been profitable and have incurred net losses in each year since the commencement of our operations. Our net losses were $18.4 million and $13.1 million for the years ended December 31, 2012 and 2013, respectively. As of December 31, 2013, we had an accumulated deficit of $128.7 million. 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. In our report on our consolidated financial statements for the year ended December 31, 2013, our independent registered public accounting firm

Table of Contents

Index to Financial Statements

included an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. See Liquidity and Capital Resources and Note 1 to Notes to Consolidated Financial Statements for additional information describing the circumstances that led to the inclusion of this explanatory paragraph.

In July 2012, we initiated a restructuring that included a reduction in workforce, decrease in office and lab space occupied, and a related sublease of the vacated space resulting in an aggregate restructuring charge of $0.9 million. We have completed all restructuring activities, and recognized all anticipated restructuring charges in the years ended December 31, 2012 and 2013. See Note 14 to our consolidated financial statements for additional information.

We have no manufacturing facilities and all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party clinical research organizations, or CROs, to carry out our clinical development and we do not yet have a sales organization. We will need substantial additional funding to support our operating activities and adequate funding may not be available to us on acceptable terms, or at all.

Critical Accounting Policies and Use of Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the respective reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are most critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management s judgments and estimates.

Revenue Recognition

We recognize 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. We currently generate revenue solely from funding pursuant to government contracts. Our government contracts provide us with payments for certain types of expenditures in return for research and development activities over a contractually defined period. Revenue from these government contracts are 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 we are deemed to be the principal participant in the contract arrangements because the activities under the contracts are part of our development programs. If we are 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 received in advance are recorded as deferred revenue. Management has determined that we are the principal participant under our government contract arrangements, and accordingly, we record amounts earned under the arrangements as revenue.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include certain payroll and personnel expenses, laboratory supplies, consulting costs, external contract research and

Table of Contents

Index to Financial Statements

development expenses, and allocated overhead, including rent, equipment depreciation, and utilities and relate to both programs sponsored by us as well as costs incurred pursuant to collaboration agreements and government contracts. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities on our behalf are deferred and expensed as the goods are delivered or the related services are performed.

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

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

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

Stock-Based Compensation

Stock-based compensation costs related to stock options granted to employees are measured at the date of grant based on the estimated fair value of the award, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model for stock options with time-based vesting and Monte-Carlo simulations for market-based stock option awards. The estimated grant date fair value of our employee stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards except for our market-based stock options, which are recognized over the implicit service period derived from the Monte-Carlo simulation model. Stock options we grant to employees generally vest over four years.

For non-employee stock-based awards, the measurement date on which the estimated fair value of the stock-based award is calculated is equal to the earlier of (i) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or (ii) the date at which the counterparty s performance is complete. We recognize stock-based compensation expense for the estimated fair value of the vested portion of non-employee awards in our statements of operations and comprehensive loss.

Table of Contents

Index to Financial Statements

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss, and net loss per share of common stock could have been significantly different. These assumptions include:

Fair Value of our Common Stock. Because our stock is not publicly traded, we must estimate its fair value, as discussed in Common Stock Valuations below.

Expected Term. We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in determining the fair value-based measurement of our options. Therefore, we have opted to use the simplified method for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

Expected Volatility. As we do not have a trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the weighted-average historic price volatility for a group of similar companies that are publicly traded based on daily price observations over a period equivalent to the expected term of the stock option grants. When selecting these public companies on which we based expected stock price volatility, we chose companies with comparable characteristics, including enterprise value, stages of clinical development, risk profiles and position within the industry. We did not rely on implied volatilities of traded options in our industry peers common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

Risk-free Interest Rate. The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options.

Expected Dividend Yield. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

In addition to the assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation for our awards. We will continue to use judgment in evaluating the expected volatility, expected terms, and forfeiture rates utilized for our stock-based compensation calculations on a prospective basis.

The fair value of the employee stock options was estimated using the following assumptions for the periods presented:

	Year Ended December 31,	
	2012	2013
Expected term	6.0 6.1 years	5.4 6.1 years
Expected volatility	56% 69%	68% 69%
Risk-free interest rate	0.8% 1.2%	1.2% 1.7%
Expected dividend yield	0%	0%
Expected forfeiture rate	9%	8%

Table of Contents

Index to Financial Statements

The fair value of stock options granted to non-employees was estimated using the following assumptions for the periods presented:

	Year Ended December 31,	
	2012	2013
Remaining contractual term	6.3 9.9 years	6.1 9.9 years
Expected volatility	56% 70%	68% 69%
Risk-free interest rate	0.9% 1.8%	1.1% 2.5%
Expected dividend yield	0%	0%

During the period from January 1, 2012 through December 31, 2013, we granted stock options to purchase common stock that vest upon the achievement of market-based stock price targets. For these options, we estimated the fair value on the original grant date using a Monte-Carlo simulation, and we are recognizing the stock based compensation expense over the implicit service period as derived under that simulation.

For the years ended December 31, 2012 and 2013, stock-based compensation expense was $0.8 million and $1.1 million, respectively. As of December 31, 2013, we had approximately $1.7 million of total unrecognized compensation expense, net of related forfeiture estimates, which we expect to recognize over a weighted-average period of approximately 2.4 years.

The intrinsic value of all outstanding options as of December 31, 2013 was $8.9 million based on the initial public offering price of our common stock set forth on the cover of this prospectus.

Common Stock Valuations

We are required to periodically estimate the fair value of our common stock when issuing stock options and computing our estimated stock based compensation expense. The fair value of our common stock was determined on a periodic basis by our board of directors, with the assistance of an independent third-party valuation expert. The assumptions underlying these valuations represent management s best estimates, which involve inherent uncertainties and the application of significant levels of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different. In determining the fair value of our common stock, our board of directors considered valuation methods intended to comply with Section 409A of the Internal Revenue Code that create a presumption that the resulting valuation is reasonable for federal tax purposes.

The fair value of the common stock underlying our stock options was estimated at each grant date by our board of directors. Our board of directors intended all options granted to be exercisable at a price per share not less than the estimated per share fair value of our common stock underlying those options on the date of grant. The valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, which we refer to as the Practice Aid.

The methodology to determine the fair value of our common stock included estimating the fair value of the enterprise by employing the following widely accepted valuation methods:

Option Pricing Method (OPM). Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options.

Probability-Weighted Expected Return Method (PWERM). The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Table of Contents

Index to Financial Statements

In conducting these valuations, our board of directors considered all objective and subjective factors that it believed to be relevant, including its and management s best estimates of our business condition, prospects, and operating performance at each grant date. The valuations, assumptions, and methodologies included, among other things:

- any recent contemporaneous third-party valuations prepared in accordance with the methodologies outlined in the Practice Aid;
- the prices of our convertible preferred stock sold to investors in arm s length transactions, and the rights, preferences and privileges of our convertible preferred stock as compared to our common stock, including the liquidation preferences of our convertible preferred stock;
- progress of research and development activities, including our clinical trials;
- our operating and financial performance, including our available capital resources;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of comparable companies;
- the lack of liquidity of our common stock as a private company;
- equity market conditions affecting comparable public companies;
- the achievement of development and other company milestones;
- the likelihood of achieving a liquidity event for the shares of common stock, such as an initial public offering, or IPO, given prevailing market and biotechnology sector conditions; and
- business risks.

The per share common stock value was estimated by allocating our enterprise value using the PWERM method in August 2011, August 2012, September 2013, and December 2013. In determining the fair value of our common stock, our board of directors used a combination of the IPO approach and the market multiple approach to estimate the enterprise value of our company.

PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns. We considered each of four possible categories of scenarios IPO, sale, private financing, and failure. The value per share under each scenario was then probability weighted and the resulting weighted values per share were summed to determine the estimated fair value per share of our common stock. In the failure, sale, and private financing scenarios, the value per share was allocated taking into account the liquidation preferences and participation rights of our convertible preferred stock in accordance with applicable elements of the Practice Aid. In the IPO scenarios, it was assumed that all outstanding shares of our convertible preferred stock and warrants would convert into common stock. Over time, as we achieved certain company-related milestones, the probability of each scenario was evaluated and adjusted accordingly.

In the IPO scenarios, we analyzed IPOs that had occurred since January 2010 and considered both an earlier- and a later-term IPO scenario. For the earlier IPO scenario, we relied on IPO peer group data and reviewed the pre-money IPO values of a group of companies that effectuated a recent IPO while in Phase 3 clinical development. For the later IPO scenario, we relied on valuations for companies that were in post-Phase 3 and/or had submitted their New Drug Application, or NDA, as of their IPO or that were publicly-traded and in post-Phase 3 and/or had submitted their NDA as of the date of valuation. For the various IPO scenarios, we estimated our IPO value based on the comparable company data and added our expected cash at the time of the expected IPOs.

For the sale scenarios, we analyzed merger and acquisition transactions involving certain targets that were in Phase 3 clinical development at the time of their acquisition. After deriving the present value of a future acquisition, we allocated the value per share by taking into account the liquidation preferences and participation rights of our convertible preferred stock.

Table of Contents

Index to Financial Statements

For the failure scenarios, we analyzed the possibility that our Company would fail during the next few years. Failure can be caused by regulatory, clinical, or financial reasons. We examined statistics regarding the successful outcome of clinical trials in various disease areas, provided by a Federal Trade Commission working paper. We looked specifically at trials for product candidates by small pharmaceutical companies and at trials for product candidates derived from biologicals and concluded that 54% to 70% of Phase 3 trials succeed, implying that there is a 30% to 46% chance that a single Phase 3 trial will fail.

In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

We granted stock options during the period from January 1, 2012 through the date of this prospectus as summarized below, excluding the options to purchase 187,909 shares of common stock at an exercise price equal to the initial public offering price set forth on the cover of this prospectus that were granted coincident with this offering:

Grant Date	Shares Issued	Exercise Price Per Share	Estimated Fair Value of Common Stock Per Share Used to Determine Stock-Based Compensation Expense
March 8, 2012	456,361	$ 7.26	$ 7.26
June 12, 2012	19,090	$ 7.26	$ 7.26
September 20, 2012	125,444	$ 4.73	$ 4.73
November 8, 2012	48,236	$ 4.73	$ 4.73
December 4, 2012	140,811	$ 4.73	$ 4.73
June 10, 2013	115,988	$ 4.73	$ 6.60
June 20, 2013	3,000	$ 4.73	$ 6.60
September 26, 2013	49,243	$ 6.60	$ 6.60
January 30, 2014	232,994	$ 9.24	$ 9.24

At each grant date the board of directors reviewed any recent events and their potential impact on the estimated fair value per share of the common stock. As is provided for in Internal Revenue Code Section 409A, we generally rely on our valuations for up to twelve months unless we have experienced a material event that would have affected the estimated fair value per common share.

For grants of stock awards made on dates for which there was no valuation performed by an independent valuation specialist, our board of directors determined the fair value of our common stock on the date of grant based upon the immediately preceding valuation and other pertinent information available to it at the time of grant.

August 1, 2011 Valuation. A contemporaneous valuation was performed by management and our board of directors with the assistance of an independent valuation specialist as of August 1, 2011 that determined the fair value of our common stock to be $7.26 per share. This valuation was performed in accordance with applicable elements of the Practice Aid. In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. In this valuation we used the PWERM approach with estimates of the common stock value to our stockholders under each of seven possible future scenarios, including three IPO scenarios, three merger or strategic acquisition scenarios and one failure scenario, depending on the success of our product candidates in clinical trials during the ensuing three years. We applied a discount of 37% to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

Table of Contents

Index to Financial Statements

Our board of directors determined there were no events or circumstances that warranted a change in fair value from the August 1, 2011 valuation at each of the grant dates of stock options that took place from August 1, 2011 through June 12, 2012.

August 31, 2012 Valuation. A contemporaneous valuation was performed by management and our board of directors with the assistance of an independent valuation specialist as of August 31, 2012 that determined the fair value of our common stock to be $4.73 per share, a decrease of $2.53 from the August 2011 valuation. The change in valuation reflected changes in the underlying assumptions regarding potential outcomes for an IPO or a merger or acquisition transaction for us. The August 31, 2012 valuation involved two IPO scenarios, one sale scenario, one Series D financing scenario and one failure scenario. We estimated the per share common stock fair value by allocating the enterprise value using the PWERM approach for the August 2012 valuation as described above. In the potential future private financing scenario, we used the OPM to estimate the common stock value using informed assumptions for an upcoming preferred stock round. In each scenario where present value calculations were required we used a risk-adjusted rate of return, as determined using the capital asset pricing model, of 21% to reflect risks associated with achievement of clinical goals and of being a clinical development company. We applied a discount of 37% to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

Our board of directors determined there were no events or circumstances that warranted a change in the fair value from the August 31, 2012 valuation at each of the grant dates of stock options that took place from August 31, 2012 through December 31, 2012.

September 24, 2013 Valuation. We estimated that our common stock had a value of $6.60 per share as of September 24, 2013, an increase of $1.87 from the prior August 31, 2012 valuation. In this contemporaneous valuation we used both the PWERM and OPM approach with estimates of the common stock value to our stockholders under each of seven possible future scenarios, including two IPO scenarios: 60% probability of an earlier IPO; 13% probability of a later IPO following a mezzanine financing round; 13% probability of the later IPO following a venture capital round of financing; and lower probabilities for a strategic acquisition in June 2015 following a mezzanine financing round, a strategic acquisition in June 2015 following a venture capital round of financing, a company failure following a mezzanine financing round, or company failure following a venture capital round. In establishing this exercise price, our board of directors considered input from management, including the valuation of our common stock as of the prior valuation date in August 2012, as well as the objective and subjective factors described above, including:

- capital market conditions for biotechnology companies continued to improve as evidenced by a recent increase in the number of IPOs and their valuations, including increased valuations;
- the NASDAQ Biotechnology (^NBI) index increased 17% from July 1, 2013 to September 30, 2013;
- an increase in the likelihood of our board of directors pursuing an IPO as determined during board meetings conducted in September 2013; and
- a decrease in the time to a prospective liquidity event.

We applied a discount of 17% to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

December 31, 2013 Valuation. We estimated that our common stock had a value of $9.24 per share as of December 31, 2013, an increase of $2.64 from the September 24, 2013 valuation. In this contemporaneous valuation we used both the PWERM and OPM approach with estimates of the common stock value to our stockholders under each of seven possible future scenarios, including two IPO scenarios: 70% probability of an earlier IPO; 13% probability of a later IPO following a pharmaceutical company partnership; 6.5% probability of the later IPO following a venture capital round of financing; and lower probabilities for a strategic acquisition in September 2015 following a venture capital round of financing, a company failure following a pharmaceutical

Table of Contents

Index to Financial Statements

company partnership, or company failure following a venture capital round. In establishing this exercise price, our board of directors considered input from management, including the valuation of our common stock as of the prior valuation date in September 2013, as well as the objective and subjective factors described above, including:

- capital market conditions for biotechnology companies continued to improve as evidenced by a recent increase in the number of IPOs and their valuations, including increased valuations;
- the NASDAQ Biotechnology (^NBI) index increased 27% from July 1, 2013 to December 31, 2013;
- an increase in the likelihood of our board of directors pursuing an IPO as a result of our filing a registration statement with the SEC in December 2013; and
- a decrease in the time to a prospective liquidity event.

We applied a discount of 12% to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

Our board of directors determined there were no events or circumstances that warranted a change in the fair value from the December 31, 2013 valuation at the grant date of stock options that took place on January 30, 2014.

Retrospective Value Used for Financial Reporting Purposes

In September 2013, we decided to pursue an IPO. As a result, in connection with the preparation of our consolidated financial statements included in this prospectus, and in preparing for our proposed IPO, we reexamined the estimated fair value of our common stock associated with our stock option grants during 2013 for financial reporting purposes as follows:

June 2013 Grants. Our board of directors granted options to purchase common stock on June 10, 2013 and June 20, 2013 to employees who were recently hired during the prior six months since we last issued option grants, with each option having an exercise price of $4.73 per share. In establishing this exercise price, our board of directors considered input from management, including the previously issued contemporaneous valuation of our common stock which was performed on August 31, 2012, as well as various objective and subjective factors including:

- the continued lack of liquidity of our common stock as a private company;
- the capital raising transactions in May 2013 that were at the same valuations as prior rounds;
- the rights, preferences and privileges of our preferred stock as compared to those of our common stock, including the liquidation preferences of our preferred stock;
- the impact of significant ongoing expenses associated with research and development and ongoing clinical trials; and
- the low likelihood of achieving a liquidity event for holders of our common stock, such as an IPO or sale of our company, given our early stage of development and prevailing market conditions.

At the time of the grants, our board of directors determined that, at the grant date, the collective effect of these events and circumstances did not indicate a significant change in the fair value of our common stock. Based on these factors, our board of directors determined that the fair value of our common stock on the grant dates listed above was $4.73 per share. In preparation for filing a registration statement with the Securities and Exchange Commission in connection with this offering, we evaluated whether or not in retrospect the value of the common stock on grant dates during 2013 was appropriate. We determine that in retrospect, the valuation of the common stock as determined by the valuation report issued on September 24, 2013 provided a closer approximation of the fair value of the common stock as it was closer to the grant date than the valuation report dated August 31, 2012. For the calculation of stock-based compensation expense for financial reporting purposes, we have used a market value of $6.60 per share for the June 2013 stock option awards.

Table of Contents

Index to Financial Statements

Income Taxes

As of December 31, 2013, we had net operating loss carryforwards of approximately $114.0 million to offset future federal income taxes and approximately $114.7 million that may offset future state income taxes. The federal and state net operating loss carryforwards are available to reduce future taxable income, if any. If not utilized, the federal and state net operating loss carryforwards will begin to expire in various amounts beginning 2023 and 2014, respectively. Current federal and state tax laws include substantial restrictions on the utilization of net operating losses and tax credits in the event of certain ownership changes. Even if the carryforwards are available, they may be subject to annual limitations, lack of future taxable income, or future ownership changes that could result in the expiration of the carryforwards before they are utilized. At December 31, 2013, we recorded a 100% valuation allowance against our deferred tax assets of approximately $54.7 million, as at that time our management believed it was uncertain that they would be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

Financial Overview and Results of Operations

General

We have not generated net income from operations and, at December 31, 2013, we had an accumulated deficit of $128.7 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including product sales, license fees, milestone payments and research and development payments in connection with strategic partnerships, our current revenue is generated solely from research and development funding pursuant to government contracts. Our product candidates are still in clinical development and may never be successfully developed or commercialized. Other than the government funding described below, 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 2017, 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. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Contract Revenue

Our contract revenue represents services performed for the development of our product candidates under government contracts. For the years ended December 31, 2012 and 2013, contract revenue was $17.9 million and $18.5 million, respectively. 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.

Biomedical Advanced Research and Development Authority (BARDA). We have received funding for our lead product candidate, plazomicin, under a contract with the Biomedical Advanced Research and Development Authority, or 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. In August 2010, BARDA awarded us a contract, which we refer to as the BARDA Contract, that included committed funding of $27.6 million for the first two years of the contract and subsequent options exercisable by BARDA to provide additional funding. In September 2012, BARDA modified the contract to increase the total committed funding to $43.4 million through March 2014. In April 2013, we were awarded an additional $60.4 million under the contract to support our Phase 3 clinical trial of plazomicin, for total committed funding of $103.8 million. Our BARDA Contract provides for payments to us based on direct costs incurred and allowances for overhead, plus a fee, where applicable. In November 2013, we modified the most recent awarded option such that payments under this option would not exceed $60.4 million, even though the cost of the Phase 3 trial and related expenses are expected to exceed the amount available to us under the BARDA Contract for direct costs incurred. We currently anticipate that the

Table of Contents

Index to Financial Statements

estimated costs of the plazomicin development program, through the receipt of top-line data, that are not funded by the BARDA Contract will approximate the allocated portion of proceeds from this offering, as described in the Use of Proceeds section of this prospectus. We intend to utilize such allocated proceeds to fund the cost of the Phase 3 trial and related expenses that are in excess of the payments to us under the BARDA Contract for the direct costs of the trial.

For the years ended December 31, 2012 and 2013, total revenue recognized under the BARDA Contract was $11.6 million and $18.1 million, respectively, of which $1.8 million and $7.2 million were included in contracts receivable at December 31, 2012 and 2013, respectively. As of December 31, 2013, a total of $39.5 million under the BARDA Contract has been recorded as revenue, with $64.3 million remaining available under the contract.

National Institute of Allergy and Infectious Diseases (NIAID). We received funding for a previous research and development program that we currently do not intend to advance, under a contract with the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, or NIH. In September 2008, NIAID awarded us a contract, which we refer to as the NIAID Contract, which as amended in September 2011 provided up to a total of $22.2 million in funding over five years through August 2013.

For the years ended December 31, 2012 and 2013, we recognized revenue under the NIAID Contract of $2.6 million and $0.2 million, respectively, of which $0.2 million and $42,000 were included in contracts receivable at December 31, 2012 and 2013, respectively.

Defense Threat Reduction Agency (DTRA). We received funding from the Defense Threat Reduction Agency, or DTRA, a division of the Department of Defense, to develop novel antibacterials for the treatment of biodefense pathogens. In June 2007, DTRA awarded us a contract, which we refer to as the DTRA Contract, that provided up to a total of $18.8 million in funding over two years. The DTRA Contract was subsequently modified to extend through the end of November 2012 and to provide for a total of $35.4 million of funding for drawdown. In November 2012, DTRA terminated the contract for convenience. In connection with the termination, we are seeking payment from DTRA for additional expenses we have incurred. We have not recognized any revenue with respect to these additional amounts. The payments we have received under the DTRA Contract are subject to an ongoing audit by the Defense Contract Audit Agency, which may reduce the size of our requested payments or require us to refund some of the amounts previously paid to us.

For the year ended December 31, 2012, we recognized revenue under the DTRA Contract of $1.5 million of which $0.8 million was included in contracts receivable at December 31, 2012. No revenue was recognized during the year ended December 31, 2013.

U.S. Army Medical Research Acquisition Authority (USAMRAA). In May 2012, we were awarded a one-year $2.5 million contract from the U.S. Army Medical Research Acquisition Authority to support our Phase 1 clinical trial of ACHN-975. Total revenue recognized was $2.2 million and $0.3 million for the year ended December 31, 2012 and 2013, respectively, of which $1.4 million and $0 were included in contracts receivable at December 31, 2012 and 2013, respectively.

Research and Development Expenses

For the years ended December 31, 2012 and 2013, research and development expenses were $26.6 million and $23.5 million, respectively. We expense both internal and external research and development costs as incurred. We currently track our external costs by project. Our external research and development expenses consist primarily of:

- 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;
- the cost of acquiring and manufacturing clinical trial and other materials; and

Table of Contents

Index to Financial Statements

other costs associated with development activities, including additional studies.

Internal research and development costs consist primarily of salaries and related fringe benefit costs for our employees (such as workers compensation and health insurance premiums), stock-based compensation charges, travel costs, lab supplies, and overhead expenses. Internal costs, except direct labor, generally benefit multiple projects and are not separately tracked by project.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue the development of our product candidates. In particular, we expect our research and development costs associated with our plazomicin program to increase significantly as our pivotal Phase 3 superiority trial progresses. As product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, we expect that our research and development expenses will increase in the future.

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. For the years ended December 31, 2012 and 2013, general and administrative expenses were $7.3 million and $7.0 million, respectively. We anticipate general and administrative expenses will increase in future periods, reflecting an expanding infrastructure and increased professional fees in preparation for becoming and operating as a public company.

Comparison of Years Ended December 31, 2012 and 2013

	Year Ended December 31,		
	2012	2013	Change
		(in thousands)	
Contract revenue	$ 17,941	$ 18,512	$ 571
Operating expenses:			
Research and development	26,581	23,484	(3,097)
General and administrative	7,349	6,992	(357)
Loss from operations	(15,989)	(11,964)	4,025
Interest income and other, net	51	193	142
Interest expense and other, net	(2,427)	(1,341)	1,086
Net loss	$ (18,365)	$ (13,112)	$ 5,253

Contract Revenue

Contract revenue in each period related solely to funding pursuant to our government contracts. Contract revenue increased $0.6 million, from $17.9 million for the year ended December 31, 2012 to $18.5 million for the comparable period in 2013. This increase was mainly attributable to an increase in research and development services performed under our BARDA Contract during 2013.

Research and Development Expenses

Research and development expenses decreased $3.1 million, from $26.6 million for the year ended December 31, 2012 to $23.5 million for the year ended December 31, 2013. This was primarily due to a $3.9 million decrease in clinical trial costs as a result of the completion of our Phase 2 clinical trial of plazomicin

Table of Contents

Index to Financial Statements

in the second quarter of 2012 and a Phase 1 clinical trial of ACHN-975 in the fourth quarter of 2012, a $1.6 million decrease in personnel-related costs as a result of a net headcount reduction of 15 employees in our research and development organization since July 2012, and a $1.0 million decrease in nonclinical research and development costs, partially offset by a $3.5 million increase in the design and start-up expenses for our Phase 3 clinical trial.

External research and development expenses for plazomicin increased $1.3 million from $10.6 million for the year ended December 31, 2012 to $11.9 million for the same period in 2013. This increase was primarily due to a $3.5 million increase in the Phase 3 trial design and start-up activities and a $0.9 million increase in consultant and manufacturing process development costs, partially offset by a $3.2 million decrease in clinical trial costs associated with the Phase 1 and Phase 2 trials. After completing our Phase 2 plazomicin clinical trial of plazomicin in the second quarter of 2012, we incurred $2.4 million and $11.7 million in plazomicin-related expenses during the years ended December 31, 2012 and 2013, respectively, for nonclinical studies on biothreat pathogens, manufacturing process development work, and the design and start-up activities for the Phase 3 clinical trial.

The following table illustrates the components of our research and development expenses during the periods indicated:

	Year Ended December 31,		Increase (Decrease)
	2012	2013	
	(in thousands)		
External research and development expenses by program:			
Plazomicin	$ 10,606	$ 11,859	$ 1,253
Other research programs	5,217	3,290	(1,927)
Subtotal external program costs	15,823	15,149	(674)
Internal costs:			
Research and development personnel costs	6,813	5,190	(1,623)
Indirect research and development expenses	3,945	3,145	(800)
Subtotal internal costs	10,758	8,335	(2,423)
Total research and development expenses	$ 26,581	$ 23,484	$ (3,097)

General and Administrative Expenses

General and administrative expenses decreased $0.3 million, from $7.3 million for the year ended December 31, 2012 to $7.0 million for the comparable period in 2013. The decrease in general and administrative expenses was primarily due to a decrease of $0.8 million in personnel-related costs from a net headcount reduction of nine employees in our general and administrative organization since July 2012, offset in part by increased consulting expenses from corporate development and finance support related activities.

Interest Expense and Other, Net

Interest expense and other, net decreased $1.1 million from $2.4 million to $1.3 million for the year ended December 31, 2012 and 2013, respectively. The decrease was primarily a result of the full amortization of the beneficial conversion features of our convertible loans with The Wellcome Trust Limited in March 2013, concurrent with the conversion of those loans into 6.4 million shares of our Series D convertible preferred stock.

Table of Contents

Index to Financial Statements

Liquidity and Capital Resources

Since our inception through December 31, 2013, we have financed our operations primarily through private placements of our equity securities, funding under our contracts with government agencies, and certain debt related financing arrangements. During 2013, we issued 2,092,572 shares of Series D convertible preferred stock at $11.99 per share, resulting in net proceeds of $22.2 million.

At December 31, 2013, we had working capital of $8.9 million and cash and cash equivalents of $10.7 million. In addition to our existing cash and cash equivalents, we have historically received funding provided under U.S. government contracts in connection with the development of our product candidates. In particular, we have received funding for our lead product candidate, plazomicin, under a contract with 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. In April 2013, we were awarded an additional $60.4 million under the contract to support our pivotal Phase 3 trial of plazomicin, for total committed funding of $103.8 million.

As a result of our recurring losses from operations and negative cash flows since inception, our independent registered public accounting firm included an explanatory paragraph raising substantial doubt as to our ability to continue as a going concern in its report on our audited consolidated financial statements for the year ended December 31, 2013. We will need to raise substantial additional funding in the near term in order to sustain operations.

Plan of Operations and Future Funding Requirements

We expect to incur substantial expenditures in the foreseeable future for the 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 pivotal Phase 3 trial of plazomicin. We believe our existing cash and cash equivalents, together with the proceeds from this offering, combined with the funds from the BARDA Contract, will allow us to fund our operating plan through at least the next 12 months. Assuming we receive the full amount of funding under the BARDA Contract, including under the unexercised option, we expect such funds, together with the proceeds from this offering, will be sufficient to fund our development of plazomicin through receipt of top-line data from our Phase 3 trial. Upon dosing our first patient in the trial, we will be obligated to make a $4.0 million payment to Isis Pharmaceuticals, Inc., or Isis, under our license agreement. See Contractual Obligations and Commitments *Other Commitments* below. However, our operating plan may change as a result of factors currently unknown to us, and we may need to seek additional funds sooner than planned. 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 will be required to obtain additional financing in the future, which we may obtain through public or private equity offerings, debt financings, a credit facility, government contracts and/or strategic collaborations. Adequate additional funding may not be available to us on acceptable terms or at all. In addition, although we anticipate being able to obtain 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. Our future financing requirements will depend on many factors, some of which are beyond our control, including:

- continued funding under our contract with BARDA;
- the size and type of the nonclinical and clinical trials 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;

Table of Contents

Index to Financial Statements

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;

the amount of funds we receive in this offering; and

the costs associated with being a public company.

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.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Year Ended December 31,	
	2012	**2013**
Net cash (used in) provided by:		
Operating activities	$ (16,762)	$ (13,854)
Investing activities	(533)	(110)
Financing activities	11,840	17,629
Net (decrease) increase in cash and cash equivalents	$ (5,455)	$ 3,665

Operating Activities

Net cash used in operating activities was $16.8 million and $13.9 million for the years ended December 31, 2012 and 2013, respectively. The primary use of cash in these periods was to fund our operations related to the development of our product candidates. Cash used for the year ended December 31, 2013 decreased compared to the same period in 2012, primarily due to lower net loss from operations.

Investing Activities

Cash used in investing activities was $0.5 million and $0.1 million for the years ended December 31, 2012 and 2013, respectively. The cash used consisted primarily of purchases of property and equipment.

Table of Contents

Index to Financial Statements

Financing Activities

Cash provided by financing activities amounted to $17.6 million for the year ended December 31, 2013. The net cash provided by financing activities for the year ended December 31, 2013 consisted primarily of the $22.2 million net proceeds from the issuance of convertible preferred stock in our Series D convertible preferred stock financing during the year, partially offset by $4.6 million for the repayment of notes payable to Oxford Finance LLC and Silicon Valley Bank.

Cash provided by financing activities amounted to $11.8 million for the year ended December 31, 2012. The net cash provided by financing activities in 2012 consisted primarily of the net proceeds from the issuance of $2.7 million of convertible notes issued to a group of existing investors in November 2012 as part of a bridge financing, $8.0 million in notes payable issued in April 2012 to Oxford Finance LLC and Silicon Valley Bank under the Loan Agreement, and $2.4 million received from our funding agreement with The Wellcome Trust, partially offset by $1.5 million for the repayment of notes payable to Oxford Finance LLC and Silicon Valley Bank.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2013:

		Payments due by period			
	Total	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years
		(in thousands)			
Lease obligations	$ 1,791	$ 439	$ 1,173	$ 179	$
Notes payable principal and interest	7,203	5,325	1,878		
Total	$ 8,994	$ 5,764	$ 3,051	$ 179	$

Lease Obligations

We lease our operating facility in South San Francisco, California under an operating lease agreement that commenced in December 2010, which covers approximately 35,000 square feet. We also sublease approximately 19,000 square feet of our leased space to a third party. In June 2013, we amended the lease to extend the term to April 2017. The lease extension does not include the space currently being subleased.

Notes Payable

In November 2011, we entered into the Loan Agreement with Oxford Finance LLC and with Silicon Valley Bank, collectively the Lenders, under which we could borrow up to $12.0 million through June 30, 2012, with $8.0 million being drawable at our option, and the remaining $4.0 million being drawable upon the occurrence of an IND event, as defined in the Loan Agreement. We borrowed $4.0 million in November 2011, and the remaining $8.0 million in April 2012. The interest rate, which was fixed at the closing of each tranche, equals the three-month LIBOR plus 7.75%. The interest rates for the loans under the Loan Agreement are 8.18% and 8.22% per annum. Payments are monthly in arrears and interest only until September 1, 2012, followed by 30 equal monthly payments of principal and interest through the scheduled maturity date of February 1, 2015. In addition, a final payment equal to 8.25% of the aggregate amount drawn will be due on February 1, 2015, or when the Loan Agreement terminates, which is being accreted as interest expense over the term of the loan using the effective-interest method. The Loan Agreement contains various covenants. As of December 31, 2013, we were in compliance with all required covenants.

In accordance with the terms of the Loan Agreement, we agreed to issue to the Lenders upon each drawdown warrants to purchase preferred stock equal to 3% of the advanced amount using a share strike price

Table of Contents

Index to Financial Statements

equal to the lower of the price per share of our Series C convertible preferred stock or the price per share in our next round of convertible preferred stock financing. During 2011 and 2012, we issued warrants to purchase 10,008 and 20,016 shares, respectively, of our Series C convertible preferred stock at an exercise price of $11.99 per share. The fair value of these warrants at the dates of issuance was approximately $86,000 and $163,000, was recorded as a debt discount within notes payable and is being amortized as interest expense over the term of the loan using the effective-interest method.

Other Commitments

We have obligations to make future payments to third parties under license agreements, including sublicense fees, royalties, and payments that become due and payable on the achievement of certain development, regulatory and commercialization milestones. However, because the achievement of these milestones is not fixed and determinable, such commitments have not been included on our balance sheet or in the Contractual Obligations and Commitments table above. In the near term, upon dosing our first patient in our Phase 3 trial for plazomicin, we will be obligated to make a milestone payment of $4.0 million to Isis pursuant to our license agreement, which we anticipate paying from our existing cash resources. For additional information regarding future payments to third parties, including milestone and royalty payments to Isis, please see Business Commercial Agreements.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our amended and restated certificate of incorporation and our amended and restated bylaws, we have indemnification obligations to our officers and directors for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. We have also entered into indemnification agreements with our directors and executive officers. There have been no claims to date, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

JOBS Act Accounting Election

The Jumpstart our Business Startups Act of 2012, or the JOBS Act, permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to opt out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to limited market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objective of our investment activities is to preserve our capital to fund our operations.

Table of Contents

Index to Financial Statements

We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. As of December 31, 2013, we had cash and cash equivalents of $10.7 million consisting of cash and money market funds deposited in highly rated financial institutions in the United States. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

We contract for the conduct of certain clinical development and manufacturing activities with vendors outside the United States. We are subject to exposure due to fluctuations in foreign exchange rates in connection with these agreements. For the year ended December 31, 2013, the effect of the exposure to these fluctuations in foreign exchange rates was not material.

We do not believe that inflation or fluctuations in foreign exchange rates had a significant impact on our results of operations for any periods presented in our financial statements.

Table of Contents

Index to Financial Statements

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel antibacterials to treat multi-drug resistant, or MDR, gram-negative infections. We are developing plazomicin, our lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae, or CRE. In 2013, the Centers for Disease Control and Prevention identified CRE as a nightmare bacteria and an immediate public health threat that requires urgent and aggressive action. We initiated a Phase 3 superiority trial of plazomicin in the first quarter of 2014. Through the Special Protocol Assessment procedure, the U.S. Food and Drug Administration, or FDA, has agreed that the design and planned analyses of our single pivotal Phase 3 trial adequately address objectives in support of a New Drug Application. We also intend to initiate a supportive efficacy trial in patients with serious CRE infections by the end of 2014. We have received FDA fast track designation for the development and regulatory review of plazomicin to treat serious and life-threatening CRE infections. Our plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority for up to $103.8 million. We have global commercialization rights to plazomicin, which has patent protection in the United States extending through 2031.

According to government agencies and physician groups, including the Centers for Disease Control and Prevention, or CDC, and the Infectious Disease Society of America, one of the greatest needs for new antibiotics is to treat CRE and other drug-resistant gram-negative pathogens. CRE leads to mortality rates of up to 50% in patients with bloodstream infections. We estimate that there were approximately 110,000 cases of CRE infections in the United States and five major markets in the European Union in 2013, with approximately one-fourth of these being bloodstream infections or pneumonia. Based on the significant increase in resistance rates in recent years, we anticipate CRE will continue to be a major health problem. For example, CDC surveillance data indicates that the rate of carbapenem resistance in *Klebsiella* species, a type of Enterobacteriaceae, increased from 1.6% to 10.4% in the hospital setting in the United States between 2001 and 2011. In Italy, *K. pneumoniae* carbapenem resistance rates almost doubled from 16% in 2010 to 31% in 2012. Governments, in collaboration with the private sector, have begun to respond by progressing regulatory reform and economic incentives to spur development of new antibiotics.

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

We consider the following to be key attributes that support the clinical utility and commercial value of plazomicin:

- Potent activity in nonclinical studies against MDR Enterobacteriaceae, including CRE.
- Demonstration of comparable efficacy to levofloxacin and acceptable safety in a Phase 2 clinical trial in patients with complicated urinary tract infections caused primarily by non-MDR Enterobacteriaceae.
- Improved dosing strategy as compared to existing aminoglycosides, and individualized patient dosing using our *in vitro* assay.
- Potential to demonstrate a mortality benefit over currently available therapy in the treatment of life-threatening CRE infections.
- Potential to reduce the healthcare costs associated with the treatment of such infections.

Table of Contents

Index to Financial Statements

Our pivotal Phase 3 trial is a pathogen-specific trial that will enroll patients with a high risk of mortality and, if successful, provide clinical evidence of the superiority of plazomicin versus the best currently available therapy for life-threatening bloodstream infections and pneumonia due to CRE. We expect to report top-line data from our Phase 3 trial in the first half of 2017, with interim analyses projected to occur in 2015 and 2016. We believe that positive efficacy data from this trial would provide the basis for FDA approval and could position plazomicin as the standard of care for the treatment of serious CRE infections. We also intend to initiate a supportive efficacy trial in patients with serious CRE infections by the end of 2014, and we expect top-line data to be available in the fourth quarter of 2015.

CRE are one of many types of MDR gram-negative pathogens threatening patients. Bacteria such as *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, and extended-spectrum beta-lactamase producing Enterobacteriaceae, each pose serious resistance threats, according to the CDC, and also drive a great need for new, safe, and effective antibiotics. We have assembled the chemistry and microbiology expertise and capabilities required to develop new agents for the treatment of gram-negative infections. Plazomicin was the first clinical candidate from our gram-negative antibiotic discovery engine. In addition, our research and development pipeline includes two antipseudomonal programs, which are programs that specifically target *P. aeruginosa* infections: a program to discover and develop small molecule inhibitors of LpxC, which is an enzyme essential for the synthesis of the outer membrane of gram-negative bacteria, and a therapeutic antibody program. We are also pursuing small molecule research programs targeting other essential gram-negative enzymes.

We have built an exceptional research and development team of approximately 30 individuals, who collectively have deep expertise in the discovery and development of new drugs from research through commercialization. Our executive team has over 60 years of combined industry experience, and a proven track record of leadership, global registration, and lifecycle management for over 20 products. Our Chief Executive Officer and Chief Medical Officer, Dr. Kenneth Hillan, held research and product development leadership roles during his career at Genentech for multiple products, including Rituxan®, Xolair®, Lucentis®, and Pulmozyme®. Becki Filice, who leads our development operations, was previously Genentech s project team leader for both Avastin® and Nutropin AQ®. Christine Murray leads our regulatory affairs and quality activities and has held key roles during the development and global registration of Viread®, Emtriva®, Truvada®, Atripla®, and Hepsera® while with Gilead Sciences.

Strategy

Our strategy is to discover, develop, and commercialize new antibacterials for the treatment of gram-negative bacterial infections. Key elements of our strategy are as follows:

Complete our pivotal Phase 3 superiority trial of plazomicin in the treatment of CRE infections and obtain regulatory approval in both the United States and the European Union. We expect to report top-line data from our Phase 3 trial and to have gathered required safety data in the first half of 2017 to support an NDA. If the trial is successful, we expect to submit a New Drug Application, or NDA, to the FDA and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, concurrently in the second half of 2017. Through the Special Protocol Assessment, or SPA, procedure, the FDA has agreed that the design and planned analyses of our pivotal Phase 3 trial adequately address objectives in support of an NDA. We have also received FDA fast track designation for the development and regulatory review of plazomicin to treat serious and life-threatening CRE infections.

Demonstrate improved clinical benefit and pharmacoeconomic advantages of our product candidates over existing therapies. By selecting product candidates with potency against MDR pathogens, we have the opportunity to demonstrate superior clinical outcomes against the current standard of care. This is in contrast to most other antibiotics currently marketed or under clinical development, which were tested, or are being tested, in non-inferiority trial designs. We also plan to demonstrate the economic benefits of our product candidates based on pharmacoeconomic outcomes such as fewer days on mechanical ventilation, less time in the ICU, or shorter total hospital stay. For example, our Phase 3 trial of plazomicin is

Table of Contents

Index to Financial Statements

designed to demonstrate improved mortality outcomes of plazomicin over comparator therapy and will allow us to assess improved pharmacoeconomic outcomes from plazomicin treatment.

Commercialize our products directly, either alone or with support from a commercialization partner, in the United States and through commercialization partners elsewhere. We have global commercialization rights to all of our drug candidates. We intend to commercialize plazomicin directly, either alone or with support from a commercialization partner, using a targeted hospital-based sales force in the United States, where CRE infections are concentrated in resistance hotspots, including New York City, Chicago, and other major population centers. Outside the United States, we intend to license full product rights to global and regional commercialization partners who can help us develop and market our products. By collaborating with companies that have an existing commercial presence and experience in targeted geographic markets, we believe we can efficiently maximize the commercial potential of our products.

Establish and leverage collaborations with non-commercial organizations for scientific expertise and funding support. We collaborate with government agencies and non-profit foundations to support our discovery efforts and advance the product candidates in our pipeline. We are currently receiving funding support for up to $103.8 million from a contract with the Biomedical Advanced Research and Development Authority, or BARDA, for the development of plazomicin as a countermeasure for diseases caused by antibiotic-resistant pathogens and biothreats, such as pneumonic plague and tularemia. We have also received funding support from government agencies such as the U.S. Department of Defense, or DOD, the U.S. National Institutes of Health, or NIH, and The Wellcome Trust, a global charitable foundation. We also partner with leading academics, scientists, and clinicians to enhance our internal discovery and development expertise, and to jointly sponsor funding proposals.

Build a portfolio of differentiated products for the treatment of MDR gram-negative infections. Since we commenced operations in 2004, we have focused on the discovery and development of antibiotics to treat gram-negative infections and have developed proprietary know-how about the relationship between compound structure and potency against gram-negative bacteria through our work on multiple antibiotic classes. We are using this expertise to build a portfolio of product candidates for the treatment of infections due to MDR pathogens. Patients with these infections often have limited or inadequate therapeutic options leading to high rates of mortality. We believe the greatest unmet medical needs lie among infections due to MDR gram-negative bacteria, where there is a significant and growing problem and the industry pipeline of drug candidates is sparse.

Antibacterials Background

Antibacterials, which we refer to interchangeably as antibiotics, are drugs used to treat infections that are caused by bacteria. The introduction of antibiotics is recognized as one of the most transformative events in medicine. Prior to the introduction of the first antibiotics in the 1930s and 1940s, bacterial infections were often fatal, and invasive surgery was accompanied by a high risk of infectious complications. Today, antibacterials are used routinely to treat and prevent infection. According to IMS Health, antibiotics accounted for $38.8 billion in sales globally in 2012, with healthcare providers prescribing 268 million courses of antibacterials in the United States alone.

There are two main varieties of bacteria, designated based on how they behave in a common laboratory staining test known as the Gram stain. Gram-positive bacteria are surrounded by a single lipid membrane and a thick cell wall. Common gram-positive pathogens include *Staphylococcus aureus* (including methicillin-resistant strains, or MRSA), *Streptococcus* species, and *Clostridium difficile*. In contrast, gram-negative bacteria are encircled by two lipid membranes, an inner membrane and an outer membrane, with a thinner cell wall in between. Gram-negative bacteria include *P. aeruginosa*, *A. baumannii*, and the Enterobacteriaceae, a family of related organisms that includes *E. coli*, *K. pneumoniae*, *Enterobacter, Salmonella,* and *Shigella* species. Drugs that act in the cytoplasm of gram-negative bacteria must cross both the inner and outer membranes, as distinct from drugs that just act on gram-positive bacteria, which only have to cross one membrane. Each membrane in

Table of Contents

Index to Financial Statements

gram-negative bacteria excludes different types of chemical entities, requiring gram-negative active antibiotics to be specifically designed to permeate both membranes. A 2007 study found that in hospital intensive care units worldwide, approximately 54% of bacterial infections were caused by gram-negative organisms and 41% by gram-positive organisms, with the remainder caused by other types of bacteria.

Antibiotics are evaluated according to several criteria:

Spectrum. Antibiotics that are effective against a wide variety of bacteria, including both gram-negative and gram-positive organisms, are considered to be broad-spectrum, while those that act upon only a limited number of species are considered to be narrow-spectrum. Narrow-spectrum antibiotics are most often selected if a specific pathogen is suspected or confirmed.

Cidality. Antibiotic action generally falls into two categories: bacteriostatic and bactericidal. Bacteriostatic antibiotics halt the growth of bacteria, allowing the human immune system to clear the infection. Bactericidal antibiotics kill the bacterial pathogen directly.

Microbiological activity. Also referred to as potency, this is the ability of the antibiotic to kill or inhibit growth of bacteria *in vitro*. *In vitro* experiments and assays are performed outside of a complex organism such as an animal or human, and include bacterial growth inhibition assays conducted in the laboratory. Potency is commonly expressed as the minimum inhibitory concentration, or MIC, in μg/mL, which is the lowest concentration at which the drug inhibits growth of the bacteria. Antibiotics with lower MICs are considered to be more potent.

Susceptibility/non-susceptibility. The relationship between microbiological activity and the clinical utility of an antibiotic in the hospital setting can be described in terms of susceptibility or non-susceptibility. A susceptible MIC value means an antibiotic can be used to treat a particular infection. A non-susceptible MIC value from *in vitro* testing means the antibiotic should not be used to treat the infection because the antibiotic is unlikely to be effective against the causative pathogen. These values are established by medical standards organizations including the Clinical Laboratory and Standards Institute, or CLSI, and the European Committee on Antimicrobial Susceptibility Testing, or EUCAST.

Resistance. Resistance refers to the inability of an antibiotic to effectively control bacterial growth. Some bacteria are naturally resistant to certain types of antibiotics. Resistance can also occur due to genetic mutations or changes in gene expression. Mechanisms responsible for resistance are often found together and can be transferred between different bacteria, leading to multi-drug resistance.

New Antibiotics Are Needed for Resistant Gram-negative Infections

According to the CDC, at least two million people each year in the United States acquire serious infections with bacteria that are resistant to one or more of the antibiotics designed to treat those infections, and each year, over 20,000 patients in the United States die from these infections. In the European Union, the annual burden posed by resistant healthcare associated bacterial infections is approximately 2.5 million hospital days and 25,000 deaths. Similar problems exist throughout the world, and the World Health Organization has declared antibiotic resistance a threat to global health security. The development and spread of resistance is driven by the use of antibiotics. Once they arise, resistant bacteria can be transferred between patients and antibiotic resistance mechanisms can be transferred between bacterial species, thus increasing the problem.

Antibiotic-resistant infections not only cause significant morbidity and mortality, but also place a substantial cost burden on the healthcare system. In most cases, antibiotic-resistant infections require prolonged and/or costlier treatments, extend hospital stays, and necessitate additional doctor visits and healthcare expenditures compared with infections that are easily treatable with antibiotics. The CDC estimates that the excess annual cost resulting from these infections in the United States is as high as $20 billion. According to an estimate from a 2012 study of over 5,500 U.S. patients, the average incremental per-patient hospital cost for antibiotic-resistant healthcare-associated infections, as compared to antibiotic-susceptible infections, was over $15,000.

84

Table of Contents

Index to Financial Statements

According to government agencies and physician groups such as the CDC and the Infectious Disease Society of America, one of the greatest needs is for new antibiotics to treat infections caused by drug-resistant gram-negative pathogens, including CRE, *P. aeruginosa*, and *A. baumannii*. These pathogens are associated with significant mortality, as growing antibiotic resistance has left limited effective treatment options. There have been few approvals for new gram-negative antibiotics in recent decades, and there are to our knowledge only three other antibiotics currently in Phase 3 development for infections due to gram-negative pathogens.

Governments, in collaboration with the private sector, have begun to respond to this significant and growing unmet medical need by progressing regulatory reform and offering economic incentives. With the passage of the Generating Antibiotic Incentives Now Act, or the GAIN Act, in July 2012, qualifying antibiotics in the United States are eligible for priority review and the potential for a five-year extension of any existing non-patent market exclusivity that has been awarded. Additionally, the FDA has issued a new draft guidance document with proposed approaches to streamline development of new antibiotics addressing serious diseases with limited treatment options. Similar developments are occurring in parallel in other regulatory bodies, most notably in Europe. Government agencies such as BARDA, the DOD s Defense Threat Reduction Agency, or DTRA, and the NIH are also providing significant funding to support the discovery and development of new antibiotics.

Our Antibiotic Discovery and Development Engine

The challenge of discovering and developing a new antibacterial for the treatment of gram-negative infections is that such treatments need to overcome resistance mechanisms to existing antibiotics and to permeate the inner and outer membranes of the bacteria. Since we began operations in 2004, we have focused on the discovery and development of antibiotics to treat gram-negative infections and have developed proprietary know-how about the relationship between chemical structure and gram-negative potency through our work on multiple antibiotic classes.

Our progress in discovering and developing gram-negative product candidates has been achieved through:

Knowledge of gram-negative antibiotic chemistry. We are able to modify the chemical structure of molecules from existing classes, such as the aminoglycosides, to avoid resistance mechanisms that inactivate other members of these classes. Further, by studying the properties of existing antibiotics that are effective against gram-negative bacteria, we believe we elucidated the first set of rules for modifying the chemical structure of compounds to increase penetration across both membranes. We are applying these rules in our discovery efforts to engineer molecules to be active against gram-negative bacteria.

Specialized compound libraries. Our chemistry libraries are designed to contain compounds that have the necessary properties for penetration of gram-negative bacteria and are used in screening campaigns against clinical isolates of MDR gram-negative pathogens.

Microbiology capabilities in clinically important pathogens. Our current focus is on today s major unmet needs such as CRE and *P. aeruginosa.* We have compiled an extensive collection of bacterial isolates, including both clinical and engineered strains, and use them to direct our modifications of compounds. Our molecular genetic expertise with these pathogens allows us to rapidly validate new antibacterial targets and determine the mode of action of our new agents across multiple pathogens.

Use of nonclinical data to predict clinical outcomes. We leverage *in vivo* animal data and computational modeling techniques to project the clinical efficacy of our early developmental candidates. *In vivo* refers to experiments and assays involving complex organisms, such as animals. As compared to other therapeutic areas, animal models of infection treatment are highly predictive of clinical efficacy. Utilizing these results, and pharmacokinetics, or PK, and safety established in initial clinical trials, we use pharmacometric modeling approaches to estimate clinical efficacy and predict our clinical dosing regimens.

Collaborations with industry-leading advisors and scientific experts. Our advisors include experts in antibacterial drug development such as Lynn Silver, Ph.D. (former Senior Investigator at Merck Research Laboratories), George H. Talbot, M.D. (Chief Medical Officer, Cerexa, acquired by Forest Laboratories),

Table of Contents

Index to Financial Statements

and Paul Reider, Ph.D. (Former Vice President, Process Chemistry at Merck and Amgen and current faculty member in the Department of Chemistry at Princeton University). We have also established collaborations with academic researchers in the field of antibiotic pharmacology, such as George Drusano, M.D., Henry Heine, Ph.D., and Arnold Louie, M.D., all with the Institute for Therapeutic Innovation, University of Florida. We maintain external collaborations with specialized scientific resources for the conduct of studies with dangerous biodefense pathogens, such as the U.S. Army Medical Research Institute for Infectious Diseases. We leverage these relationships and our own in-house expertise in biodefense countermeasure development to secure funding that supports our antibacterial programs targeting both antibiotic-resistant pathogens and biothreats.

Research and Development Pipeline

The following table summarizes the status of plazomicin and our other research programs:

Plazomicin

Overview

Our most advanced product candidate is plazomicin, a novel aminoglycoside designed by our scientists to overcome clinically relevant aminoglycoside resistance mechanisms. Aminoglycosides have been used successfully for the treatment of serious bacterial infections for more than 50 years. As a class, aminoglycosides have several important characteristics including rapid bactericidal activity, well-described PK, a lack of metabolism in humans, and excellent solubility and stability. However, the spread of resistance to currently marketed aminoglycosides has decreased their clinical utility. We developed plazomicin by chemically modifying an existing aminoglycoside, sisomicin, a natural product isolated from bacteria, to shield the regions of the molecule that are targeted by the enzymes responsible for aminoglycoside resistance. As a result of these modifications, plazomicin remains active against multi-drug resistant organisms where most other major drug classes, including commercially available aminoglycosides such as gentamicin and amikacin, have limited activity. Based on this profile, we are developing plazomicin as an intravenous, or IV, therapy for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including CRE, which the CDC considers to be one of the top three urgent resistance threats to public health.

Table of Contents

Index to Financial Statements

We consider the following to be key attributes that support the clinical utility and commercial value of plazomicin:

Potent in vitro activity and in vivo efficacy in nonclinical studies against MDR Enterobacteriaceae, including CRE. Plazomicin retains activity in nonclinical studies against clinical Enterobacteriaceae isolates possessing most varieties of carbapenem resistance mechanisms, as well as most types of resistance to other key antibiotics, including commercially available aminoglycosides, colistin, and tigecycline.

Demonstration of comparable efficacy to levofloxacin and acceptable safety in a Phase 2 clinical trial in patients with complicated urinary tract infections caused primarily by non-MDR Enterobacteriaceae. We have completed a successful Phase 2 clinical trial of plazomicin in patients with complicated urinary tract infections, or cUTI, as well as required Phase 1 PK and safety clinical trials. In patients with cUTI, plazomicin demonstrated efficacy that was similar to levofloxacin in microbiological eradication of the causative pathogen of the infection, which were primarily non-MDR Enterobacteriaceae, and in clinical outcome, specifically, resolution of baseline signs and symptoms.

Improved dosing strategy compared to existing aminoglycosides, and individualized patient dosing using our in vitro assay. We have used recent innovations in PK and pharmacodynamic, or PD, modeling to create dosing regimens designed to achieve the drug exposures in the body we project to be efficacious in treating serious CRE infections. As a consequence, plazomicin is dosed in higher amounts relative to MIC than other commercially available aminoglycosides. Patient dosing in the Phase 3 trial population will also be individualized by using a proprietary *in vitro* assay to measure levels of plazomicin in the bloodstream and adjusting the dose to achieve the targeted drug exposure.

Potential to demonstrate a mortality benefit over currently available therapy in the treatment of life-threatening CRE infections. We have designed our pivotal Phase 3 trial for plazomicin as a superiority trial with a primary efficacy endpoint of all-cause mortality at 28 days. The trial will compare a plazomicin-based regimen versus a colistin-based regimen for the treatment of CRE bloodstream infections and pneumonia. Through the SPA procedure, the FDA has agreed that the design and planned analyses of the trial adequately address objectives in support of an NDA. Most antibiotics are approved based on demonstrating non-inferiority to the current standard of care in the treatment of a specific type of infection (such as cUTI, intra-abdominal infection, and pneumonia) caused by a range of pathogens against which both the treatment and comparator are active. By focusing the Phase 3 plazomicin trial on patients with a high unmet medical need where the efficacy of the current standard of care is poor, and enrolling based on infections caused by the target pathogen (CRE), we have the opportunity to demonstrate differentiated efficacy of plazomicin in the clinical setting.

Potential to reduce the healthcare costs associated with the treatment of serious infections. Treatment of antibiotic-susceptible infections is associated with lower overall costs as compared to the treatment of antibiotic-resistant infections. Our Phase 3 trial of plazomicin will permit us to document improved pharmacoeconomic outcomes from plazomicin treatment of MDR Enterobacteriaceae, which may include fewer days on mechanical ventilation, less time in the ICU, and shorter total hospital stay.

Based on these attributes, we believe that plazomicin has the potential to become the new standard of care for the treatment of CRE.

Carbapenem-Resistant Enterobacteriaceae Pose an Urgent Threat to Patients

The need for new antibiotics to treat CRE is particularly acute, as CRE are one of the top global threats in infectious disease. In 2013, the CDC labeled CRE as nightmare bacteria and indicated that CRE pose a public health threat requiring urgent and aggressive action. These bacteria are commonly MDR, exhibiting resistance not only to carbapenems, but also to nearly all antibiotics commonly used to treat gram-negative infections, including cephalosporins, beta-lactam/beta-lactamase inhibitor combinations, fluoroquinolones, and currently-marketed aminoglycosides. Resistance to carbapenems, which we define as non-susceptibility to a carbapenem

87

Table of Contents

Index to Financial Statements

antibiotic, has been highlighted because these drugs are one of the last lines of defense against resistant gram-negative infections. Most CRE express enzymes called carbapenemases which break down the carbapenem antibiotic molecule before it can kill the bacteria. Due to the lack of effective therapies, CRE infections are associated with significant mortality, with up to 50% mortality observed in patients with bloodstream infections.

With limited treatment options available for CRE infections, physicians have resorted to older drugs such as colistin or more recently approved drugs such as tigecycline. However, there is evidence that these antibiotics are failing patients. For example, in bloodstream infections due to carbapenemase-producing *K. pneumoniae*, all-cause mortality for treatment with colistin, tigecycline, or combinations of antibiotics that do not include a carbapenem active *in vitro* against the infecting isolate were reported to be 46%, 47%, and 37%, respectively. Recently, resistance to even these last-resort treatments has begun to be reported, further increasing the urgency for new therapeutic options.

The CRE problem is global and the incidence has increased significantly over the last decade. For example, CDC surveillance data indicates that the rate of carbapenem resistance among *Klebsiella* species increased from 1.6% to 10.4% in the United States between 2001 and 2011. In Italy, 31% of *K. pneumoniae* strains were carbapenem-resistant in 2012, a sharp increase from 2010 when the rate was 16%. The problem is even more pronounced in Greece, with more than 60% of *K. pneumoniae* strains exhibiting resistance in 2012. In Latin America, 11% of *Klebsiella* species were resistant to carbapenems in Brazil, 8% in Argentina, and 5% in Chile, according to surveillance data gathered from 2008 to 2010.

We estimate that there were approximately 110,000 cases of CRE infections in the United States and five major markets in the European Union in 2013, which we refer to as the EU 5, with approximately one-fourth of these being bloodstream infections or pneumonia. We believe that CRE incidence will continue to increase in the future. A key driver of resistance growth, the use of carbapenems, is increasing. Once restricted in use to limit the emergence of resistance, hospitals are changing their policies due to the pressing need for carbapenems to treat the growing number of MDR infections. In a recent survey, two-thirds of U.S. hospital pharmacy directors reported that carbapenems are now unrestricted on their hospital formularies, likely a reflection of the increasing incidence of difficult-to-treat gram-negative infections. Additionally, the spread of CRE among patients, between healthcare facilities, and across geographic regions is exacerbated by the ability of CRE to readily transfer their resistance genes to other bacteria. Spread is especially dangerous when encountered in the outpatient setting, as it could lead to an epidemic of community-based CRE infections. Among outpatients in the United States, almost 2% of *K. pneumoniae* isolates were resistant to carbapenems in 2010, up from nearly 0% in 2005. Finally, CRE are very difficult to eradicate once they establish a foothold in the healthcare setting.

Commercial Strategy for Plazomicin in CRE

Our overall goal is to establish plazomicin as the standard of care for the treatment of serious CRE infections. Through our clinical development approach to demonstrate plazomicin s superiority to the current standard of care, and our regulatory filing strategy under an SPA, we plan to establish the utility of plazomicin in treating bloodstream infections and pneumonia caused by gram-negative bacteria. This strategy is intended to support plazomicin s differentiated profile from both approved and development-stage antibacterials.

We believe that the commercial opportunity for plazomicin will be significant if our pivotal Phase 3 superiority trial demonstrates a mortality benefit against currently available antibacterial treatment. To our knowledge, plazomicin would be the first antibiotic to be approved on the basis of such a design. We anticipate that the expected mortality benefit of plazomicin will create significant physician demand for plazomicin based on our primary market research. A demonstrated mortality benefit in a patient population with a high risk of death, and a potential to circumvent spread of CRE in the hospital setting, will be key product differentiators that drive adoption. We intend to achieve our pricing and reimbursement objectives through demonstration of a mortality benefit in CRE patients as well as through demonstration of significant pharmacoeconomic cost savings to the healthcare system with the use of plazomicin. At a 2013 forum sponsored by The Pew Charitable Trusts, a

Table of Contents

Index to Financial Statements

nonprofit organization, which brought together payors, the FDA, and industry, panelists supported an approximate price points of $15,000 per treatment course for new antibacterial agents for resistant infections as long as clinical and economic benefits were clearly demonstrated. We will collect data in our Phase 3 trial that is designed to enable us to compare medical resource utilization between patients treated with plazomicin and those treated with comparator therapy. For example, we will determine whether plazomicin-based therapy results in fewer days on mechanical ventilation, less time in the ICU, and shorter total hospital stays. As a reference for the potential cost-savings that could accumulate, a study using 2002 cost data estimated that the total cost of a single day in the ICU without mechanical ventilation was over $3,000, and that the incremental cost of a day of mechanical ventilation in the ICU was over $1,500. Accordingly, we believe an effective treatment for CRE infections has the potential to yield substantial cost-savings relative to existing therapy based on these key cost drivers.

We expect physicians will use plazomicin for definitive treatment of patients with CRE infections, as well as for empiric treatment, or treatment prior to definitive confirmation of the pathogen, of patients who are at risk of CRE. Definitive treatment for CRE begins when the infecting pathogen has been confirmed as CRE. Assuming success of our Phase 3 trial as currently designed, definitive treatment with plazomicin is expected to last between 7 to 14 days. We estimate that there were approximately 110,000 cases of confirmed CRE infections in the United States and the EU 5 in 2013, with approximately one-fourth of these cases being bloodstream infections or pneumonia. Given the importance of providing effective CRE therapy as soon as possible in order to reduce the risk of death, we believe physicians will use plazomicin empirically to treat patients who are at a high risk of CRE infection. Empiric treatment continues until the pathogen is confirmed, which typically takes 2 to 3 days. Following pathogen confirmation, definitive treatment begins either with the same drug(s) used for empiric treatment or with different drug(s), depending on numerous factors including the identity and susceptibility of the pathogen, as well as patient response to empiric therapy. We estimate the total number of pneumonia or bloodstream infections treated empirically in the US and the EU 5 was approximately four million in 2013. We estimate that approximately 850,000 of these empirically treated cases involved consultation with an infectious disease physician, a proxy for the number of more complicated cases or serious infections, including suspected MDR infections. This smaller subset of empirically treated patients is a more relevant population in which plazomicin might be prescribed to provide empiric treatment for CRE, depending on a number of CRE risk factors, including patient colonization with CRE and high incidence of CRE in the hospital unit.

We intend to focus our initial commercial efforts on the U.S. market, which we believe represents the largest single market opportunity for plazomicin. We plan to use a targeted U.S. sales force to promote plazomicin to hospital-based healthcare professionals in resistance hotspots either alone or with support from a commercialization partner. In key markets outside of the United States, including Europe, Asia, and Latin America, we believe we can maximize the value of plazomicin through licensing full product rights to one or more commercialization partners who have local market expertise.

Plazomicin Development Program

We are developing plazomicin, our lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including CRE. We have not 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. However, based on the strength of our nonclinical data against CRE, and supported by the clinical pharmacokinetic, efficacy and safety data generated by our completed clinical trials, including our successful Phase 2 trial evaluating the efficacy of plazomicin compared with levofloxacin in patients with cUTI, the FDA agreed through the SPA procedure and other communications that our single pivotal Phase 3 trial, a total safety database of approximately 300 patients, and additional nonclinical studies would be acceptable to support an NDA for plazomicin. While we were originally developing plazomicin for a broad range of gram-negative infections, including cUTI, we recognized it had exciting potential to address the urgent public health threat of CRE that has emerged in recent years. We also received FDA fast track designation for plazomicin for the treatment of serious and life-threatening CRE infections. We believe our planned development program, if

Table of Contents

Index to Financial Statements

successful, will also be acceptable to support a marketing application for plazomicin in the EU, based on feedback obtained through the EMA scientific advice procedure.

Key elements of our program to develop plazomicin for the treatment of CRE infections are outlined in the table below:

CRE Clinical Program

Phase	Objectives	Planned Enrollment (approximate)	Initiation of Top-Line Data	Receipt of Top-Line Data
3	*Primary*: Demonstrate superiority of plazomicin as compared to colistin with respect to all-cause mortality at 28 days in patients with serious CRE infections *Secondary*: Safety, PK of plazomicin	360	Q1 2014	1H 2017
Supportive Efficacy Trial	Evaluation of efficacy and safety of plazomicin in patients with serious CRE infections	50	Q4 2014	Q4 2015
Safety Trial	Demonstrate safety of plazomicin in patients with serious CRE infections	70	2H 2015	1H 2017

Nonclinical Studies Supporting Success of CRE Program

Study	Methods	Key Result
In vitro activity against CRE	Standard microbiology assays	Plazomicin demonstrated strong potency against CRE isolates resistant to other antibiotics.
In vivo efficacy against CRE	Mouse models of lung and thigh muscle infection	Plazomicin demonstrated strong efficacy against CRE, including as compared to colistin or tigecycline.
In vivo efficacy against plague and tularemia	Non-human primate models of pneumonic plague and tularemia	Animals receiving plazomicin demonstrated survival at doses below the level equivalent to our Phase 3 clinical dose.
In vivo and *in vitro* toxicology studies	*In vitro* and animal model studies of toxicities and potential side effects	Plazomicin demonstrated impacts on kidney function similar to other aminoglycosides. No other significant effects were observed.

Table of Contents

Index to Financial Statements

Completed Phase 1 and Phase 2 Clinical Studies

Study No.	Objectives	Number Enrolled	Key Result
001	Phase 1 trial of safety and PK after single and multiple doses in healthy subjects	39	Plazomicin was well tolerated at doses of up to 15 mg/kg for 3 days.
003	Phase 1 trial of safety, plasma PK and lung penetration in healthy subjects	40	Plazomicin was well tolerated at doses of up to 15 mg/kg for 5 days. Plazomicin penetrated into the lung.
004	Phase 1 trial of safety and PK in healthy and impaired kidney function subjects	24	As with other aminoglycosides, plazomicin s dose needs to be adjusted in patients with moderately or severely impaired kidney function.
006	Phase 1 thorough QT/QTc trial in healthy subjects[1]	64	Plazomicin showed no clinically relevant potential to increase risk for cardiac arrhythmias at single doses of up to 20 mg/kg.
002	Phase 2 safety, efficacy, and PK in patients with cUTI	145	Plazomicin displayed efficacy similar to the comparator antibiotic treatment (levofloxacin). Plazomicin was generally well tolerated at doses of up to 15 mg/kg for 5 days.

[1] *The thorough QT/QTc study is used to determine whether or not the effect of a drug on the QT/QTc interval in target patient populations should be studied intensively during later stages of drug development. The QT/QTc interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart s electrical cycle.*

Pivotal Phase 3 Superiority Trial of Plazomicin for the Treatment of CRE

Given the critical need for new drugs to treat infections caused by CRE and given plazomicin s differentiated *in vitro* activity and *in vivo* efficacy against this pathogen, we have designed our pivotal Phase 3 trial to position plazomicin as a superior drug for the treatment of CRE. By focusing on the pathogen against which plazomicin has superior nonclinical activity, instead of a broader population of pathogens, we believe we have a greater probability of demonstrating the clinical differentiation of plazomicin. In addition, unlike most antibiotic trials that are designed to show non-inferiority to the current standard of care, this trial is a superiority study with a primary efficacy endpoint of all-cause mortality at 28 days. This superiority approach is consistent with recent FDA draft guidance regarding the development of antibacterial therapies to treat patients with unmet medical need. We have reached agreement with the FDA through the SPA procedure on the design and planned analyses of this pivotal Phase 3 trial.

We initiated our global Phase 3 trial for the treatment of serious CRE infections in the first quarter of 2014. We expect to have top-line data from this pivotal Phase 3 trial and to have gathered requisite safety data by the first half of 2017. If the trial is successful, we expect to submit an NDA to the FDA and an MAA to the EMA in the second half of 2017, and subsequently submit marketing applications in other global regions. Our Phase 3 trial for plazomicin will be funded in part by BARDA, which has awarded us an option for $60.4 million in funding for the trial, as part of our $103.8 million contract.

Trial Design

Our pivotal Phase 3 trial is a randomized, open-label superiority trial of the efficacy and safety of plazomicin as compared to colistin when each is combined with a second antibiotic in the treatment of patients with bloodstream infections or hospital-acquired pneumonia due to CRE. The trial will enroll patients whose causative pathogen is either presumed or confirmed to have an MIC ³ 4 µg/mL for the broadest spectrum carbapenems, which are referred to as type 2 carbapenems. These patients are reported to have high mortality

Table of Contents

Index to Financial Statements

rates when treated with currently available therapeutic options, providing us with the opportunity to demonstrate a statistically significant improvement in mortality with plazomicin.

The following figure provides an overview of our pivotal Phase 3 superiority trial:

Patients with presumed or confirmed infection with CRE based on local laboratory testing will be enrolled and randomized 1:1 to a plazomicin- or colistin-based regimen. Presumed CRE infections are those with a high probability of being CRE based on diagnostic testing (for example, preliminary susceptibility testing or demonstration of the presence of a carbapenemase), while confirmed CRE infections for purposes of our Phase 3 trial are those with isolates confirmed to have an MIC ³ 4 µg/mL to a type 2 carbapenem. At the time of randomization, one adjunctive antibiotic, either tigecycline or meropenem, will be selected by the investigator to be combined with plazomicin or colistin.

The trial will enroll patients with serious CRE infections that are associated with significant mortality. The enrollment criteria, also referred to as inclusion/exclusion criteria, seek to identify patients most likely to derive a survival benefit from efficacious antibacterial therapy. Only patients who have received less than 72 hours of empirical therapy for presumed or confirmed CRE infection will be eligible for the trial. The trial excludes patients with colistin resistant infections, refractory septic shock, or specified clinical syndromes that require more than 14 days of antibiotic therapy. We are also using the Acute Physiology and Chronic Health Evaluation II, or APACHE II, score, a measure of the severity of disease that ranges from 0 to 71, as part of our enrollment criteria. Higher APACHE II scores correspond to more severe disease and a higher risk of death. Patients will be eligible for enrollment with an APACHE II score from 15 to 30.

We will stratify patients for factors that could independently impact mortality in order to minimize the risk for a baseline imbalance between the treatment arms. Patients will be stratified by infection type (bloodstream or pneumonia), APACHE II score, and time from the initiation of empirical therapy for the patient s infection to randomization for this trial.

Patients randomized to plazomicin will receive an initial dose up to 15 mg/kg as a 30-minute IV infusion. The initial dose and dosing interval will be determined by baseline renal function. Subsequent plazomicin doses

Table of Contents

Index to Financial Statements

will be individualized based on changes in renal function and by therapeutic drug management, or TDM, using our *in vitro* assay.

Colistin will be administered in the form of its IV prodrug as a 5 mg/kg IV loading dose followed by maintenance dosing of 5 mg/kg divided every eight or every 12 hours for up to 14 days. Colistin dosing will be adjusted according to renal function.

The trial comprises a screening period of up to 72 hours, an active-treatment period of 7 to 14 days, and a post-treatment period through the end of study on Day 28. Efficacy will be determined by assessments of survival, clinical response, and microbiological response. The primary efficacy endpoint is all-cause mortality at 28 days. Secondary efficacy parameters include time to death through Day 28, all-cause mortality at 14 days after randomization and assessment of clinical response at end of treatment, test of cure, and end of study. Additional efficacy endpoints include early assessment of the resolution of fever, improvement of oxygenation in pneumonia patients, and clearance of bacteremia in patients with bloodstream infections. Microbiological assessments include the evaluation of microbiological response and the incidence of development of decreased susceptibility to plazomicin or colistin.

Prior to the completion of enrollment, an independent data monitoring committee will conduct and review two unblinded interim analyses of efficacy and futility. The interim analyses will occur when 33% and 67% of the required patients in the primary analysis population have reached the end of study on Day 28, which we anticipate to occur in 2015 and 2016, respectively. The interim analyses will determine whether the trial should be stopped early based on either efficacy or futility criteria.

Dosing Strategy for Phase 3 Using Pharmacometric Modeling

We used recent innovations in PK/PD modeling to predict that the plazomicin dosing regimen in the Phase 3 trial will be adequate for efficacious treatment of CRE infections. This approach integrates information on the distribution of MICs for the target pathogen based on recent microbiology surveillance data, the results of exposure-response assessments in animal models, and PK data from our Phase 1 and 2 trials to define the appropriate dosing regimen for efficacy. Based on this analysis, we predict that with our Phase 3 dosing regimen 92% of patients will achieve the levels of plazomicin in their blood or lung tissue associated with successful treatment of CRE infection *in vivo*. Compared to exposures achieved with current dosing of other aminoglycosides, the targeted plazomicin exposure is typically two to three times higher relative to the MIC of the infecting pathogen.

In addition, dosing of plazomicin in our Phase 3 trial will be individualized for each patient based on changes in renal function and by TDM. The use of TDM for currently marketed aminoglycosides, combined with real-time PK assessments, has been shown to help achieve target drug exposures, leading to improved patient outcomes and reduced length of hospital stays. Plazomicin concentration in plasma will be determined using an investigational *in vitro* assay. In November 2013, we received an Investigational Device Exemption, or IDE, approval from the FDA for use of the assay in the trial.

Projected Mortality Benefit of Plazomicin

To estimate the potential size of the treatment effect for plazomicin over colistin in our pivotal Phase 3 superiority trial, we performed a meta-analysis of data from three observational studies describing the clinical outcome of 309 patients with bloodstream infections due to carbapenemase-producing Enterobacteriaceae. We segregated patients into two groups:

High MIC : Patients whose infections were caused by an isolate with a carbapenem MIC ³ 4 µg/ml, our target MIC for inclusion in our Phase 3 trial, and who received combination antibiotic therapy.

Low MIC : Patients whose infections were caused by an isolate with a carbapenem MIC < 4 µg/ml, and who received combination antibiotic therapy containing a carbapenem.

Table of Contents

Index to Financial Statements

We observed a 35% mortality rate in the High MIC group and a lower 14% mortality rate in the Low MIC group. We interpret the absolute mortality difference of 21% (95% confidence interval: 11%-30%) between the two groups to be an indication of the potential magnitude of the treatment effect that might be observed when an effective antibiotic therapy is used to treat patients whose isolates have a carbapenem MIC ³ 4 µg/ml.

Our trial design assumes a more conservative treatment effect size than suggested by this meta-analysis. Specifically, we assumed that a plazomicin-based regimen would result in a 12% absolute reduction in mortality from a baseline mortality rate of 35% in the colistin comparator group. Based on this projection, as well as additional statistical considerations, we estimate that the trial will need to enroll 286 treated patients with laboratory confirmed CRE infections to complete the primary analysis population. We estimate that it will require approximately 360 randomized patients over a 36-month period to reach this enrollment target.

Additional Efficacy and Safety Trials

We are planning a single-arm open-label trial evaluating plazomicin in the treatment of serious CRE infections. We are targeting an enrollment of approximately 50 patients to be treated with plazomicin. The goal of the trial is to provide earlier evidence that we believe would support safety and efficacy based on the evaluation of clinical and microbiological outcomes. We expect the trial to begin in late 2014 with top-line data available in the fourth quarter of 2015.

We also intend to conduct an additional safety trial to supplement the Phase 3 and supportive efficacy trials in order to complete the safety database of 300 patients treated with plazomicin as agreed with the FDA to support the NDA. The trial will be a single-treatment arm safety trial. We expect to initiate this safety trial following our first interim analysis of the Phase 3 trial in 2015. Our BARDA contract includes an unexercised option for additional funding to support this safety trial, among other things. The dollar value of this unexercised option has not yet been determined.

We will continue to monitor changes in the competitive landscape and new opportunities that may result from regulatory reform regarding approval pathways for new antibiotics. As appropriate, we may consider performing additional clinical trials if we believe such trials might result in more rapid regulatory approval of plazomicin or our other product candidates.

Nonclinical Data Support the Use of Plazomicin for the Treatment of CRE Infections

Plazomicin has been tested extensively *in vitro*, in animal efficacy models, and in safety pharmacology and toxicology studies. As noted above, nonclinical assays are generally predictive of clinical efficacy for antibacterials, particularly in the case of a well understood class such as aminoglycosides.

In vitro Activity Against MDR Enterobacteriaceae, Including CRE

Results from multiple susceptibility testing studies against MDR Enterobacteriaceae demonstrate that plazomicin remains potent against strains resistant to several other classes of antibiotics, including carbapenems and other aminoglycosides. We can determine the likely activity of plazomicin against MDR Enterobacteriaceae, including CRE, encountered in the hospital setting globally by testing a large number of clinical isolates collected from unique patients with different types of infections from hospitals around the world.

Table of Contents

Index to Financial Statements

In these studies, we measured the potency of each drug by determining the concentration of drug required to inhibit the growth of 50% and 90% of the isolate set. We refer to these measurements as the MIC_{50} and MIC_{90}, respectively. The table below summarizes the *in vitro* activity of plazomicin and several other commercially-available antibiotics from various different drug classes commonly used to treat Enterobacteriaceae infections against a large number of clinical CRE isolates.

Compound	Class	N	MIC_{50} (µg/mL)	MIC_{90} (µg/mL)
Plazomicin	Aminoglycoside	807	0.5	2
Gentamicin	Aminoglycoside	807	4	128
Amikacin	Aminoglycoside	806	32	64
Ciprofloxacin	Fluoroquinolone	767	8	8
Ceftazidime	Cephalosporin	510	64	>128
Piperacillin/tazobactam	Beta-lactam/Beta-lactamase inhibitor	731	>128	>128
Tigecycline	Glycycline	723	1	2
Colistin/polymyxin B	Polymyxin	692	1	4

Key:

Susceptible	Non-susceptible

N=number of strains within the overall set of 807 strains tested vs. the given antibiotic.

Notes: CLSI 2012 susceptibility criteria were used except for tigecycline and colistin, for which EUCAST 2013 criteria were used because CLSI criteria were not available. Isolates selected had an MIC ³ 2 µg/mL for any type 2 carbapenem, a value defined as non-susceptible for this class according to CLSI 2012 susceptibility criteria. Plazomicin has not yet been assigned susceptibility criteria by these organizations.

As shown in this table, at least 50% of the tested isolates were non-susceptible to all of the marketed drugs except for gentamicin, tigecycline, and colistin, while plazomicin remained potent (MIC of 0.5 µg/mL or less). This shows the high degree of multi-drug resistance in CRE and the reason tigecycline and colsitin are considered among the only options for treatment of infections caused by CRE. All of the MIC_{90} values of the marketed drugs were non-susceptible, meaning that a significant percentage of infections caused by these isolates would be untreatable with available antibiotics. Plazomicin maintained an MIC_{90} of 2, meaning that at least 90% of these isolates were inhibited by a concentration of 2 µg/mL or less. Overall, 96% of these isolates had a plazomicin MIC of 2 µg/mL or less.

Table of Contents

Index to Financial Statements

The graphs below display the activity of each of plazomicin and two commercially available aminoglycosides, amikacin and gentamicin, against clinical isolates of Enterobacteriaceae that are resistant to carbapenems due to the expression of two of the three main types of carbapenemases, serine carbapenemase and oxacillinase. The MIC of each of the tested drugs is expressed along the horizontal axis of the graph and the percent of the strains inhibited by the tested drug at a given MIC is expressed along the vertical axis. The number specified in the title indicates the number of strains that were included in each study.

As exemplified in the above graphs, plazomicin retained activity against 90% or more of the tested isolates at an MIC of less than or equal to 1 μg/mL. Amikacin and gentamicin display poor activity overall because the tested strains also expressed aminoglycoside resistance mechanisms.

The following set of graphs displays the activity of each of plazomicin, amikacin, and gentamicin against clinical isolates of Enterobacteriaceae that are resistant to carbapenems due to the expression of the third main type of carbapenemase, metallo-beta-lactamase, or MBL. Activity against isolates with NDM-1, which is a particular type of MBL, is shown separately from isolates with other MBLs.

Plazomicin retained activity with an MIC of less than or equal to 1 μg/mL against 90% or more of the tested isolates with an MBL, except for those with NDM-1, where plazomicin was only active against one of the 17 isolates tested. Plazomicin, amikacin, and gentamicin each display very poor activity against the NDM-1 isolates because this resistance mechanism and a particular aminoglycoside resistance mechanism, ribosomal methyltransferase, commonly occur together in the same isolate. Ribosomal methyltransferase, which renders plazomicin and most commercially available aminoglycosides inactive, and NDM-1 are generally limited to some countries in Asia, including India, although there have been isolated cases of infections by bacteria carrying such resistance mechanisms elsewhere, including the United States.

We also studied the activity of plazomicin *in vitro* against eight clinical CRE isolates in combination with meropenem and tigecycline, as we are planning to use plazomicin in combination with these two antibiotics during our Phase 3 trial. In our studies, we did not observe any reduced activity of plazomicin in combination with either of these antibiotics.

Table of Contents

Index to Financial Statements

In vivo Efficacy Against CRE

Plazomicin has demonstrated efficacy against CRE in multiple efficacy studies in animal models, and was consistently more potent than either tigecycline or colistin at doses equivalent to the clinical dose for each drug. In these studies, the PK of plazomicin was measured so the effect of its concentration in blood or lung tissue could be evaluated. Because animals and humans metabolize and excrete drugs at different rates, the dose of plazomicin was humanized so the concentration of plazomicin over time in the animal closely matched the human concentration over time measured from our clinical studies. We used two different mouse models of bacterial infection in which a measured amount, or inoculum, of a CRE strain was introduced into either the thigh muscle or lung of the animal, allowed to grow for two hours, and then treated with an antibiotic for one day. We determined efficacy in the animal model by measuring the amount of bacteria, expressed as colony-forming units per gram (CFU/g), in treated as compared to untreated tissues, and then comparing either the increase or decrease in the amount of bacteria versus the original inoculum, or stasis.

The graph below shows the results of plazomicin, colistin administered as its prodrug used in the treatment of patients, and tigecycline against eight CRE strains in a mouse thigh infection model.

For these thigh infection studies, we selected CRE isolates from hospitalized patients that were primarily susceptible (MIC £ 1 µg/mL) to colistin and tigecycline by EUCAST criteria. The MICs of the antibiotics against the eight tested CRE isolates are shown in the table below.

	Number of Strains with the Given MIC	
	£ 1 µg/mL	**³ 2 µg/mL**
Plazomicin	8	0
Colistin	6	2
Tigecycline	7	1

Plazomicin demonstrated efficacy by reducing the amount of bacteria by up to 100 times compared to the original inoculum at doses lower than the equivalent clinical dose. In contrast, colistin and tigecycline displayed poor efficacy, despite having MICs against most of the isolates at or below the value considered to be susceptible. This result is consistent with the high mortality rates observed when colistin and tigecycline are used to treat serious CRE infections.

Table of Contents

Index to Financial Statements

Efficacy Against Rapidly Lethal Plague and Tularemia Pneumonia in Non-Human Primate Models

Plazomicin has demonstrated efficacy in non-human primate models against infections caused by the biothreat pathogens *Yersinia pestis* and *Francisella tularensis*. These two bacteria species are considered potential bioweapons and are the causative agents for plague and tularemia, respectively. The primary site of infection in these models is the lung, and the pathogens cause a rapidly lethal pneumonia that spreads to other organs in the absence of effective therapy. In these models, animals were exposed to an aerosol spray of the pathogen and monitored for signs of fever indicating an active infection. PK was also measured. Once fever was detected, treatment was started with either a fixed dose of plazomicin (six animals for each treatment group) or a placebo and continued for 10 days. In one arm of the tularemia study, treatment was withheld until 24 hours after fever was observed allowing additional time for the infection to establish and worsen. Across these studies, almost all plazomicin-treated animals were cleared of their bloodstream and lung infections even when dosed below levels equivalent to our Phase 3 clinical dose. However, in the plague studies some plazomicin-treated animals died due to infections that spread to the central nervous system, or CNS, where we believe plazomicin does not penetrate. Like other aminoglycosides, intravenous plazomicin would not be suitable for the treatment of CNS infections. In contrast, none of the placebo control-treated animals in these studies survived. The strong efficacy of plazomicin against these diseases in a primate model suggests that it would likely be effective in similar serious infections in humans. Our BARDA contract includes an unexercised option for funding, among other things, additional non-human primate studies of plazomicin s efficacy against *Yersinia pestis* and *Francisella tularensis*. The dollar value of this unexercised option has not yet been determined.

Nonclinical Safety Studies

We have studied plazomicin in industry-standard *in vitro* and *in vivo* toxicology models designed to characterize the potential side effects and safety parameters of drugs. These studies are typically required by regulatory agencies such as the FDA prior to use of the drug in humans. In our studies, plazomicin s primary toxicological effect was on the kidney. In animals, damage to the kidney increased and organ function deteriorated in proportion to plazomicin dose. This effect was observed to be reversible. After plazomicin dosing ceased, kidney function returned to normal or near normal, and the kidney damage was repaired. These results are consistent with the nonclinical toxicity and clinical safety of other aminoglycosides. Reversible kidney toxicity is a known side effect of these drugs. In head to head studies in animals, we observed the relationship between plazomicin dose and effect on the kidney and its function to be similar to that of gentamicin.

Aminoglycosides are also associated with hearing loss and impaired balance. Both of these functions are controlled by organs in the inner ear. To evaluate the potential for hearing loss with plazomicin treatment, we studied plazomicin in an animal model designed to detect hearing loss associated with drug treatment. In this study, plazomicin did not impact hearing function or cause detectable damage to the inner ear. The ability of this model or other available nonclinical models to predict drug-related hearing loss has not been firmly established. Therefore, we carefully monitored hearing and balance in our completed clinical trials of plazomicin.

Additional Nonclinical Studies to Support an NDA

We intend to conduct additional nonclinical studies to support an NDA for plazomicin. We plan to perform further microbiological studies of plazomicin in order to assess its activity against contemporary clinical isolates of Enterobacteriaceae and other bacterial species from the United States and other countries. We plan to conduct these studies no earlier than three years prior to the NDA filing. Our BARDA contract includes an unexercised option for additional funding to support these studies. The FDA has agreed that these additional nonclinical studies, when combined with our single pivotal Phase 3 trial and a total safety database of approximately 300 patients, would be acceptable to support an NDA for plazomicin. Other studies we plan to conduct include industry-standard experiments to characterize the distribution and excretion of plazomicin *in vivo*, as well as *in vitro* studies of the potential for plazomicin to interact with enzymes associated with drug distribution and metabolism.

Table of Contents

Index to Financial Statements

Plazomicin Clinical Data Are Supportive of Further Trials of Plazomicin in Patients with CRE

Our clinical trial data to date for plazomicin indicate an acceptable safety profile, predictable PK, and lung penetration that is similar to other aminoglycosides. In addition, our Phase 2 trial demonstrates that plazomicin has microbiological and clinical efficacy in treating cUTI that is similar to levofloxacin, an approved antibiotic in the fluoroquinolone class commonly used in hospitals for the treatment of this infection.

Plazomicin has been studied in four Phase 1 clinical trials and one Phase 2 clinical trial. To date, a total of 239 healthy subjects and patients have received plazomicin at doses ranging between 1 and 20 mg/kg administered as an IV infusion. In the Phase 1 trials, 82 subjects received 15 mg/kg administered either as a single dose or once daily for up to five days. In the Phase 2 trial, 74 patients with cUTI received 15 mg/kg of plazomicin administered once daily for up to five days.

Phase 1 Clinical Trials

In our Phase 1 trials we demonstrated that plazomicin displays good tolerability and safety in single doses up to 20 mg/kg and multiple doses of up to 15 mg/kg of plazomicin administered once daily for five days. Common adverse events in the Phase 1 studies (occurring at a frequency greater than 5% in all subjects) were headache, numbness or tingling, dizziness, nausea, and drowsiness. All adverse events were mild or moderate in severity, and the overall frequency of events was similar between the plazomicin and placebo groups. In a substudy of our second Phase 1 trial (003) that investigated lung penetration of plazomicin, five subjects experienced mild to moderate transient hypotension at the end or soon after a single dose, consisting of a 10-minute infusion of 15 mg/kg of plazomicin. Following this trial, the infusion period was increased to 30 minutes for all subsequent trials. In a focused cardiovascular trial, plazomicin showed no clinically significant potential to cause arrhythmias, and all adverse events were mild or moderate in severity.

Pharmacokinetic data collected in these trials showed dose proportionality and linearity in plasma within the tested plazomicin dose range. Lung penetration of plazomicin based on epithelial lining fluid, or ELF, levels was similar to the range of values reported for amikacin, another aminoglycoside agent, in bronchial secretions of normal and infected subjects. Phase 1 trials also showed that, as with other aminoglycosides, plazomicin is mainly cleared through the kidneys. A trial in subjects with moderate or severe kidney function impairment confirmed that plazomicin PK is significantly altered in these subjects relative to subjects with mild or normal kidney function. This trial demonstrated that, as with other aminoglycosides, dose adjustment will be necessary in patients with moderate or severe impairment.

Phase 2 Clinical Trial

Our Phase 2 multicenter, double-blind, randomized, active comparator-controlled trial, evaluated the efficacy of plazomicin compared with levofloxacin in 145 patients with cUTI including acute pyelonephritis. We selected cUTI as the target infection for our Phase 2 trial because cUTIs are one of the most common hospital-acquired infections, and the majority of cUTIs across all geographic regions are caused by Enterobacteriaceae, most commonly *E. coli*. We selected levofloxacin as the comparator drug for this trial since it is considered an empiric standard of care for cUTI and it shares many similar properties to plazomicin, such as concentration-dependent killing of bacteria, once-daily dosing, and achievement of high urinary concentrations.

During the first phase of the trial, patients were randomized 1:1:1 to 10 mg/kg plazomicin, 15 mg/kg plazomicin, or 750 mg levofloxacin, each treatment being administered once daily for five consecutive days. During the second phase of the trial, the 10 mg/kg treatment arm was eliminated and patients were randomized 2:1 to 15 mg/kg plazomicin or levofloxacin 750 mg.

Efficacy was assessed through microbiological and clinical outcomes at end of treatment, at test of cure, and at a long-term follow-up visit. The primary efficacy endpoint was the proportion of patients who attained microbiological eradication at the test of cure visit. This endpoint was determined for two analysis populations: a

Table of Contents

Index to Financial Statements

modified intent-to-treat, or MITT, population which included all randomized patients with at least one causative pathogen isolated from an acceptable urine specimen before treatment; and a microbiologically evaluable, or ME, population which was a smaller subset of the MITT population and included patients who met key study inclusion criteria, received study treatment for a pre-specified duration and had an acceptable urine specimen at test of cure.

As shown in the table below, the proportion of patients who achieved microbiological eradication was similar for each of the plazomicin (10 mg/kg and 15 mg/kg) and levofloxacin treatment groups in both analysis populations. Microbiological eradication rates for the MITT population in our Phase 2 trial were lower than the ME population. This is in part due to the fact that the MITT population, but not the ME population, had a proportion of patients with an unknown/indeterminate microbiologic outcome primarily because samples at the test of cure visit were not obtained.

By-Patient Microbiological Response [1]	**Plazomicin 10 mg/kg**	**Plazomicin 15 mg/kg**	**Levofloxacin 750 mg**
Microbiologically Evaluable (ME)			
N	7	35	21
Eradication, n (%)	6 (85.7%)	31 (88.6%)	17 (81.0%)
95% CI	42.1% 99.6%	73.3% 96.8%	58.1% 94.6%
Difference (95% CI)[2]			7.6% (31.3%, 16.0%)
Modified Intent-to-Treat (MITT)			
N	12	51	29
Eradication, n (%)	6 (50.0%)	31 (60.8%)	17 (58.6%)
95% CI	21.1% 78.9%	46.1% 74.2%	38.9% 76.5%
Difference (95% CI)[2]			2.2% (27.2%, 22.9%)

[1] N = number of patients in the treatment group; n=number of patients within a specified microbiological response category.

[2] Difference in microbiological eradication rates between levofloxacin 750 mg and plazomicin 15 mg/kg as calculated by the levofloxacin eradication percentage minus the plazomicin 15 mg/kg eradication percentage. The 95% CI for the difference is based on a normal approximation with a continuity correction.

The secondary efficacy endpoint of the trial was clinical outcome. In the plazomicin and levofloxacin treatment groups, a majority of the clinically evaluable patients (66.7% 78.6%) were assessed as cured, with resolution of baseline signs and symptoms of infections. Results for the ME and MITT groups were similar. The majority of isolates collected from patients in these populations during the trial were non-MDR Enterobacteriaceae.

Table of Contents

Index to Financial Statements

Overall in the Phase 2 trial, plazomicin administered at doses of 10 or 15 mg/kg once daily for five days was generally well tolerated. There were no serious adverse events assessed as related to treatment with plazomicin. Five patients (four in the plazomicin 15 mg/kg group and one in the levofloxacin group) prematurely discontinued study drug due to adverse events. Overall, adverse events were experienced by 7 of 22 patients (31.8%) in the plazomicin 10 mg/kg groups, 26 of 74 patients (35.1%) of patients in the plazomicin 15 mg/kg group, and 21 of 44 patients (47.7%) in the levofloxacin 750 mg group. Most of these were assessed as mild or moderate in severity. Adverse events occurring in at least two patients are shown in the table below.

Adverse Event, number of patients (%)	Plazomicin 10 mg/kg (22 patients)	Plazomicin 15 mg/kg (74 patients)	Levofloxacin 750 mg (44 patients)
Headache	2 (9.1%)	6 (8.1%)	3 (6.8%)
Diarrhoea	0 (0.0%)	4 (5.4%)	2 (4.5%)
Dizziness	0 (0.0%)	4 (5.4%)	0 (0.0%)
Nausea	0 (0.0%)	4 (5.4%)	0 (0.0%)
Vomiting	0 (0.0%)	4 (5.4%)	1 (2.3%)
Gastritis	1 (4.5%)	2 (2.7%)	0 (0.0%)
Abdominal pain upper	0 (0.0%)	1 (1.4%)	1 (2.3%)
Cough	1 (4.5%)	1 (1.4%)	1 (2.3%)
Dyspepsia	1 (4.5%)	1 (1.4%)	1 (2.3%)
Dyspnoea	1 (4.5%)	1 (1.4%)	0 (0.0%)
Hypokalaemia	0 (0.0%)	1 (1.4%)	2 (4.5%)
Insomnia	0 (0.0%)	1 (1.4%)	1 (2.3%)
Dysgeusia	0 (0.0%)	0 (0.0%)	2 (4.5%)
Hypertension	1 (4.5%)	0 (0.0%)	1 (2.3%)
Pruritus	1 (4.5%)	0 (0.0%)	2 (4.5%)
Tachycardia	1 (4.5%)	0 (0.0%)	1 (2.3%)
Upper respiratory tract infection	0 (0.0%)	0 (0.0%)	2 (4.5%)

The hearing and balance of patients were closely assessed, as aminoglycosides are known to have safety liabilities associated with these functions. One plazomicin-treated patient reported mild transient vertigo and another plazomicin-treated patient reported mild unilateral tinnitus that persisted and was considered permanent. Neither patient tested positive for changes in hearing function or balance. Kidney function as measured by mean serum creatinine values remained generally stable over the trial. Two patients treated with 15 mg/kg plazomicin had adverse events associated with renal function. Both events were assessed as mild in severity and involved increases in serum creatinine of 0.5 mg/dL and 0.7 mg/dL respectively, which returned to near-baseline values by the last follow-up visit. Two additional patients treated with 15 mg/kg plazomicin experienced serum creatinine abnormalities (an increase from 1.2 to 2.0 mg/dL and an increase from 0.8 to 1.5 mg/dL), neither of which were classified as adverse events, and that returned towards baseline at the last follow-up visit.

The results of this Phase 2 trial demonstrated the efficacy of plazomicin in patients with cUTI that was similar to the efficacy of levofloxacin in terms of achieving both microbiological eradication of the causative pathogen of the infection and clinical cure. Furthermore, plazomicin was generally well tolerated in this patient population.

Antipseudomonal Discovery and Development Program

Beyond our plazomicin program, our research team is focused on discovering medicines with novel mechanisms of action for serious infections caused by MDR *Pseudomonas aeruginosa.* This pathogen is one of the most common causes of healthcare-associated infections and was responsible for approximately 20% of the three million hospital-treated pneumonia cases in the United States, EU and Japan in 2012. According to the CDC, approximately 13% of healthcare-associated infections caused by *P. aeruginosa* are multi-drug resistant, and these infections are associated with high morbidity and mortality rates, as well as increased healthcare costs.

Table of Contents

Index to Financial Statements

As a result, the CDC has categorized *P. aeruginosa* as a serious threat requiring prompt and sustained action. We are taking a multifaceted approach to identify new antipseudomonal agents through our small molecule drug and therapeutic antibody discovery programs.

We expect to nominate at least one clinical candidate from our antipseudomonal program in 2014 and to file an IND in 2015. Based on our current operating plans and our planned use of proceeds from this offering, we anticipate that advancement of more than one clinical candidate to an IND will require additional funding.

Small Molecule Drug Discovery Program

In 2006, we initiated a program to identify inhibitors of LpxC. LpxC is an essential enzyme for the formation of bacterial membranes in gram-negative bacteria that is highly conserved among gram-negative species. Inhibition of LpxC disrupts the structural integrity of the outer bacterial membrane, reducing its capacity to protect the cell and retain vital molecules in the space between the outer and inner membrane, leading to bacterial cell death.

Using our discovery engine, we made improvements to known LpxC inhibitors to generate a series of promising molecules that showed greater activity against gram-negative pathogens, improved safety in preclinical models, and better pharmaceutical properties. Given their novel mechanism of action, compounds generated in this program demonstrate no cross-resistance with current antibiotics and therefore retain activity against strains harboring resistance mechanisms that inactivate many other marketed antibiotics. This is illustrated in the figure below with respect to the most advanced compound in this program, ACHN-975, which demonstrates potent activity against a large set of almost 1,000 *P. aeruginosa* clinical isolates. The figure also shows the potency of other antibiotics commonly used to treat infections caused by *P. aeruginosa* infections. For these drugs, the dotted lines begin at the MIC value considered non-susceptible, according to 2012 CLSI criteria, demonstrating the current scarcity of effective therapeutic options for *P. aeruginosa* infections. None of the other drugs had a susceptible MIC_{90} against the test set.

In 2012, we conducted a first-in-human Phase 1 clinical trial of ACHN-975, which demonstrated linear, dose-dependent PK and good tolerability when administered intravenously in single doses at levels predicted to be effective in treating *P. aeruginosa* infections. In a subsequent multiple-dose trial, the first three subjects that received multiple doses of ACHN-975 developed inflammation at the infusion site, with venous thrombosis at the infusion site in one of these subjects, and the trial was terminated early. No subjects had signs or symptoms of a systemic inflammatory reaction and no other safety findings were observed. All three subjects were discharged from the Phase 1 unit after demonstrating resolution or substantial improvement of the infusion site reactions. We are working to establish

Table of Contents

Index to Financial Statements

preclinical models that reproduce this toxicity. If we are able to validate a model, we intend explore alternative formulations or prodrugs of ACHN-975 to address the local infusion site tolerability. We also have several backup compounds that we may turn to if the reformulation and prodrug efforts are unsuccessful.

Therapeutic Antibody Discovery Program

Therapeutic monoclonal antibodies, or mAbs, have several distinguishing features that make them attractive as antibacterial agents. First, we believe they will not be impacted by resistance mechanisms that inactivate existing small molecule-based antibiotics. Second, they are highly specific to their target, greatly reducing the potential for toxicity due to off-target binding. Third, humanized or fully human mAbs are well tolerated with low immunogenicity in patients. Finally, mAb therapeutics can achieve sustained exposure with a typical half-life of around 3 weeks, potentially enabling an antibacterial antibody to prevent or cure an infection following a single intramuscular or intravenous dose.

Our goal is to generate mAbs that can be deployed as a monotherapy to treat infections caused by MDR *P. aeruginosa*. Many of the antibacterial antibodies currently in development by others will likely be limited to prophylactic use for preventing infections or require adjunctive therapy with an effective antibiotic. Based on our experience developing agents for gram-negative pathogens, we have identified a set of targets and a corresponding screening funnel for each target that we believe to be well suited for therapeutic mAb discovery. Our unique approach has the potential to transform the way gram-negative infections are treated by enabling a safe, single-dose primary cure of infection or long-lasting step-down therapy upon discharge from the hospital.

Additional Gram-negative Discovery and Development Program

We are drawing on knowledge gained through our work on LpxC inhibitors to identify compounds that bind and inhibit additional essential enzymes in the gram-negative outer membrane biosynthesis pathway. These targets are attractive for many of the same reasons as LpxC: their inhibition leads to rapid cell death, they are highly conserved among the gram-negative bacteria, and they have no similar mammalian genes, reducing the potential for mechanism-based toxicity in patients. We are seeking to identify these compounds by using structure-guided design and virtual fragment screening based on the crystal structures of these enzymes.

Another one of our programs seeks to identify compounds that bind and inhibit a metabolic enzyme that is essential to gram-negative bacteria. The starting point for this medicinal chemistry campaign is a published series of molecules known to bind the target enzyme, but lacking in microbiological activity against pathogens of interest. We are deploying our discovery platform to design and synthesize novel molecules based on published structural information with enhanced gram-negative activity. We have generated a set of novel compounds with improved activity compared to published compounds against our key target gram-negative species (for instance, MICs of 0.5 μg/mL and 2 μg/mL against wild-type *E. coli* and *K. pneumoniae*, respectively), and have identified several lead compound series for further optimization. This improvement in activity has reinforced our understanding and proprietary knowledge of this space, and further validated our small molecule discovery approach.

Government Contracts

BARDA

Our program to develop plazomicin for the treatment of CRE infections of the bloodstream and lung, as well as for disease caused by certain bacterial biothreat pathogens, is partially funded under a contract with BARDA. This contract was awarded in August 2010 and consists of a base amount as well as three options, two of which have been exercised. The base amount and the two exercised options total $103.8 million of committed funding, of which $39.5 million has been recorded as revenues as of December 31, 2013, with $64.3 million remaining available. The potential funding amount under the unexercised option has not yet been determined. The

Table of Contents

Index to Financial Statements

unexercised option relates to the conduct of an open-label safety trial, certain nonclinical studies to support an NDA and certain nonclinical biodefense studies, all of which are discussed above, and we anticipate that BARDA will evaluate award of this option by mid-2015.

Overall, the contract calls for the development, manufacturing, nonclinical and clinical evaluation of, and regulatory filings for, plazomicin as a countermeasure for diseases caused by antibiotic-resistant pathogens. These pathogens include bacteria associated with serious hospital-acquired infections, such as CRE, as well as biothreats, such as *F. tularensis*, which causes tularemia, and *Y. pestis*, which causes plague. As the prime contractor, we are responsible for all technical and regulatory activities under a research plan proposed by us and accepted by BARDA. From time to time, we may propose a change to the research plan to BARDA, and BARDA may or may not choose to accept the change to the research plan, along with any associated additional costs, subject to the availability of funding, as well as other factors. We are also obligated under the contract to satisfy various federal reporting requirements, including technical reporting with respect to our plazomicin development activities, reporting with respect to intellectual property and financial reporting. In addition, technical documents and regulatory filings may be reviewed by BARDA prior to their finalization and/or submission.

Payments under the contract with BARDA are made in installments as activities are conducted in accordance with the research plan. Payments to us are based on direct costs incurred and allowances for overhead, plus a fee, where applicable. In November 2013, we modified the most recent awarded option such that payments under this option would not exceed $60.4 million, even though the cost of the Phase 3 trial and related expenses are expected to exceed the amount available to us under our BARDA contract for direct costs incurred. We currently anticipate that the estimated costs of the plazomicin development program, through the receipt of top-line data, that are not funded by our BARDA contract will approximate the allocated portion of proceeds from this offering, as described in the Use of Proceeds section of this prospectus. We intend to utilize such allocated proceeds to fund the cost of the Phase 3 trial and related expenses that are in excess of the payments to us under our BARDA contract for the direct costs of the trial. Under standard government contracting terms, the government receives only limited rights for government use of certain of our pre-existing data and certain data produced with non-federal funding, to the extent such data are required for delivery to BARDA under the project. The U.S. government receives unlimited rights to use and disclose new data first produced under the project with BARDA funding. The U.S. government is entitled to a nonexclusive, worldwide, royalty-free license to practice or have practiced any patent on an invention that is conceived or first reduced to practice under the project, and may obtain additional rights if we do not elect to retain ownership of a subject invention or if we do not satisfy certain disclosure and patent prosecution obligations with respect to a subject invention. The government s rights do not include the composition of matter patents related to plazomicin, as these were developed and prosecuted prior to our entry into the BARDA contract and without government funding. The BARDA contract does not entitle the government to any sales royalties or other post-commercialization financial rights.

BARDA is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond current year amounts allotted from Congressionally approved annual appropriations.

DTRA

In June 2007, we entered into a contract with DTRA to develop novel antibacterials for the treatment of biodefense pathogens. To date, we have received $33.5 million out of $35.4 million that was available for drawdown under this contract. In November 2012, DTRA terminated this contract for convenience. We are seeking payment from DTRA for additional expenses we have incurred in connection with this contract. We have not recognized any revenue with respect to these additional amounts. The payments we have received under the DTRA contract and the payments we are requesting are subject to an ongoing audit by the Defense Contract Audit Agency.

The DTRA contract related to the funding of our LpxC program, including ACHN-975. Under the contract s terms, the U.S. government received rights to use and disclose new data first produced under the project with DTRA funding only to the extent they are related to government applications connected with certain select

Table of Contents

Index to Financial Statements

pathogens. In addition, the U.S. government is entitled to a nonexclusive, worldwide, royalty-free license to practice or have practiced any patent on an invention that was conceived or first reduced to practice under the project, including the composition of matter patent related to ACHN-975, and may obtain additional rights if we do not elect to retain ownership of a subject invention or if we do not satisfy certain disclosure and patent prosecution obligations with respect to a subject invention.

NIAID

In September 2008, we entered into a five-year contract with the U.S. National Institute of Allergy and Infectious Diseases, or NIAID, to develop novel antibacterials for the treatment of biodefense pathogens. We received over $21.0 million under this contract, which supported a previous research and development program that we currently do not intend to advance. Our NIAID contract expired in August 2013. The U.S. government retains certain rights to data and intellectual property generated under the contract.

USAMRAA

In May 2012, we entered into a one-year contract with the U.S. Army Medical Research Acquisition Authority, or USAMRAA. Under the contract we conducted the first-in-human single ascending dose study of ACHN-975. The total amount of the contract was $2.5 million, and the contract expired in May 2013. The U.S. government retains certain rights to data generated under the contract.

For more information regarding the government contracts referred to above see Risk Factors Risks Related to Our United States Government Contracts and Risk Factors Risks Related to Intellectual Property *Provisions in our United States government contracts, including our contract with BARDA, may affect our intellectual property rights*.

Commercial Agreements

ARK Diagnostics, Inc. Development Services Agreement

In August 2013, we entered into a development services agreement with ARK Diagnostics, Inc., or ARK. Under this agreement, we and ARK are co-developing an *in vitro* assay to measure levels of plazomicin in the blood to enable patients to receive safe and efficacious doses of plazomicin. Such an assay would be used to provide therapeutic drug management, or TDM. ARK is responsible for the manufacture and supply of the developed assay for our plazomicin Phase 3 trial program. Depending on the mutually agreed regulatory approval pathway and commercialization strategy for the assay, we will be required to pay ARK up to an aggregate amount of between $1.0 million and $1.6 million in milestone payments for the achievement of certain development, manufacturing and regulatory milestones, $0.7 million of which have been achieved and paid as of the date of this prospectus. Intellectual property rights relating to the assays developed under the contract are jointly owned by us and ARK, but each party retains ownership of its background intellectual property and improvements thereto.

In addition to the co-development activities performed under the agreement, we are required to negotiate in good faith the terms of an agreement for the commercialization of the assay based upon certain core terms outlined in the development services agreement to be included in such a commercialization agreement. Such core terms include that ARK would have 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 step-in rights to commercialize the assay in the United States and the EU if ARK elects not to do so. If we do not agree with ARK on the terms of a commercialization agreement by April 2014, then either we or ARK can request the appointment of an expert panel to establish any unresolved terms of such commercialization agreement, and the panel decision on such unresolved terms would be binding on ARK and on us. The development services agreement provides that if, by

Table of Contents

Index to Financial Statements

January 2016, we have still not agreed the terms of a commercialization agreement with ARK, ARK will provide us with an interim supply of the finished assay for at least two years following the approval of the NDA for plazomicin and interim supply of components to the assay to have the assay made for us by a third party for a further three years, until five years following the approval of the NDA, at a price that is comparable with the pricing offered by ARK to other distributors. If we still have not agreed with ARK on the terms of a commercialization agreement by January 1, 2018, then at our request, we, ARK and a third-party supplier reasonably acceptable to ARK shall enter into a technology transfer and license agreement, whereby on commercially reasonable terms, ARK would grant to the third-party supplier a license under ARK s applicable intellectual property and perform a transfer of know-how to such third-party supplier, solely to the extent necessary for the purpose of manufacturing and supplying the assay to us for use or commercialization by us and our designees.

The development services agreement will expire upon the later of the completion of the development services and January 1, 2020. Either we or ARK may terminate for the other party s uncured material breach, and we may terminate without cause upon 60 days written notice to ARK.

License Agreement with Isis Pharmaceuticals, Inc.

On January 25, 2006, we entered into a license agreement with Isis Pharmaceuticals, Inc., or Isis, pursuant to which Isis granted us an exclusive license under certain patents relating to aminoglycoside antibacterial compounds and related know-how to develop and commercialize certain novel aminoglycoside antibacterial compounds. We are required to use commercially reasonable efforts to develop and commercialize licensed compounds under the agreement. In consideration for the rights granted to us by Isis under the license agreement, we issued $1.5 million of our Series A convertible preferred stock to Isis in 2006. In addition, we are required to make payments to Isis upon the achievement of specified development and regulatory milestones totaling up to $19.5 million for the first aminoglycoside product developed under the agreement, including a payment of $4.0 million to Isis upon dosing the first patient in our Phase 3 trial of plazomicin, and up to $9.75 million for the second aminoglycoside product developed under this agreement, and to pay Isis a low double-digit share of non-royalty sublicensing revenues that we receive from sublicensees for the grant of sublicenses under our agreement with Isis, provided that the maximum amount we are required to pay Isis with respect to the sum of all development and regulatory milestones and non-royalty sublicensing revenue payment obligations for plazomicin, as the first aminoglycoside product under the agreement, is $19.5 million. Likewise, our cumulative development and regulatory milestone payment and non-royalty sublicensing revenues payment obligations for a second aminoglycoside product under the agreement with Isis will not exceed $9.75 million. To date, we have made development milestone payments of $3.0 million to Isis with respect to plazomicin, $2.5 million of which was paid in cash and $0.5 million of which was paid in the form of our Series B convertible preferred stock. We are also required to pay additional milestone payments of up to $20.0 million in the aggregate upon the first achievement of specified threshold levels of annual net sales of all aminoglycoside products in a calendar year. If any aminoglycoside product, including plazomicin, is successfully commercialized, we will be required to pay royalties to Isis in the low single digits on worldwide net sales of licensed products by us, our affiliates and sublicensees.

Our license agreement with Isis will continue for as long as we are obligated to pay royalties to Isis, which will be on a product-by-product basis until the later of (a) ten years from the date of first commercial sale of an aminoglycoside product covered by the agreement in the United States, Japan or Europe; and (b) the abandonment, revocation, invalidation or expiration of the last valid claim of a patent covered under the agreement which covers such product, not to exceed twenty years after the first commercial sale in the United States, Japan or Europe. Either party may terminate the agreement for the uncured material breach of the other party, and Isis may terminate the agreement if we fail to make timely payments, subject to a specified cure period. We may also terminate the agreement or the license with respect to a particular product without cause upon 60 days notice.

Table of Contents

Index to Financial Statements

License Agreement with the University of Washington

On December 1, 2006, we entered into a license agreement with the University of Washington, or UW, pursuant to which UW granted us an exclusive license under UW s rights to certain patents and technology covering novel LpxC inhibitor antibacterial compounds, subject to UW s retained right to use such patents and technology for research and academic purposes. UW also granted us a non-exclusive license in related know-how. Certain of the patents and technology licensed under our agreement with UW were originally claimed to be co-owned or solely owned by Novartis. Subsequently, we, Novartis and UW acknowledged and agreed that such patents and technology are co-owned by Novartis and UW. Therefore, the exclusivity of our license is subject to Novartis rights to use the licensed patents and technology and to grant licenses to others to do so. This agreement was amended in March 2009 to modify the timing of our reimbursement of certain patent prosecution expenses, and in January 2011 to amend the timing of certain milestone events. We are required to use commercially reasonable efforts to commercialize the licensed technology and to manufacture and maximize the sales of licensed products. In consideration for the rights granted to us by UW under the license agreement, we paid an up-front cash payment to UW upon execution of the agreement. In addition, if we achieve specified development and regulatory milestones, we will be required to make payments to UW totaling up to $2.15 million for the first product under the agreement to achieve the specified milestone, $150,000 of which has already been paid with respect to ACHN-975, and up to $1.075 million for each of the second and third products to achieve the specified milestone. In addition, if ACHN-975 or any other LpxC inhibitor covered under the agreement is successfully commercialized, we will owe UW a royalty in the low single digits based on worldwide net sales, if any, of licensed products by us and our sublicensees, subject to a requirement to pay to UW a minimum annual royalty following regulatory approval, and, beginning in 2009, a nominal annual license maintenance fee prior to regulatory approval. We are also obligated to pay UW a share of non-royalty sublicensing revenues that we receive from sublicensees for the grant of sublicenses under this agreement, ranging from the mid-single digit to very-low-double digit percentages of such revenues, based on timing of the execution of the sublicense.

The UW Agreement will continue until expiration of the last valid claim of a patent covered under the agreement, which we expect to occur no later than January 2024. However, UW has the right to terminate the agreement if we breach it and fail to cure such breach within a specified cure period or upon our insolvency. We may terminate this agreement for any reason upon 30 days notice to UW.

Competition

The pharmaceutical industry is very competitive and subject to rapid and significant innovation. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies, universities, and other research institutions. Many of our competitors have greater financial resources, as well as larger research and development staff and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are superior to, or more effectively marketed than, plazomicin or any other drug candidate that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

The competition in the antibiotics market is intense. We are initially developing plazomicin as a treatment for presumed or confirmed bloodstream or pneumonia CRE infections, and if approved, plazomicin will face competition from commercially available antibiotics such as tigecycline, which is marketed by Pfizer as Tygacil, other aminoglycosides that are generically available (e.g., gentamicin, amikacin, tobramycin), and polymyxins that are generically available (colistin and polymyxin B).

Table of Contents

Index to Financial Statements

In addition, if approved, plazomicin may face additional competition from antibiotics currently in clinical development. We are aware of other antibiotics currently in development. Forest Laboratories and AstraZeneca are developing ceftazidime/avibactam and ceftaroline/avibactam for pneumonia and complicated urinary and intra-abdominal infections. Tetraphase Pharmaceuticals is developing eravacycline for cUTI and intra-abdominal infections. The Medicines Company is developing Carbavance for complicated urinary tract infections and MDR gram-negative infections, including CRE.

If approved, we believe that plazomicin would compete effectively against both marketed and known pipeline competitors based on the following:

- Potent *in vitro* and *in vivo* activity against CRE, including strains bearing all classes of carbapenemases;
- Activity in the presence of a range of resistance mechanisms, including most aminoglycoside modifying enzymes, fluoroquinolone target site mutations, extended-spectrum beta-lactamases, and carbapenemases;
- Registrational program focused on bloodstream and pneumonia infections due to CRE;
- Superiority trial design with all-cause mortality endpoint; and
- Acceptable safety and tolerability profile.

If we are unable to demonstrate these or other advantages of plazomicin over competing drugs and drug candidates, we may not be able to successfully commercialize plazomicin and our results of operations may suffer. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make plazomicin or any other product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or regulatory approval or discovering, developing and commercializing antibiotics before we do.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We have sought patent protection in the United States and certain other jurisdictions for plazomicin, ACHN-975, and certain other inventions to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets relating to our proprietary technology platform that may be important to the development of our business.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, see Risk Factors Risks Related to Intellectual Property.

Plazomicin (Aminoglycoside)

The patent portfolio for plazomicin is based upon an Achaogen-owned patent family that includes patents and patent applications directed to plazomicin and structural analogs thereof, pharmaceutical compositions containing plazomicin or analogs thereof, and methods of using plazomicin or analogs thereof in the treatment of

Table of Contents

Index to Financial Statements

bacterial infections. As of January 31, 2014, this patent family included one U.S. patent (U.S. Patent No. 8,383,596, issued February 26, 2013, which we refer to herein as the 596 patent), one pending U.S. patent application (Application Serial No. 13/734,729, filed January 4, 2013) and fourteen corresponding foreign patents and patent applications. As of January 31, 2014, we had corresponding granted patents in Australia, China, Eurasia, Japan, and Korea. In addition, as of January 31, 2014, we had corresponding patent applications pending in Brazil, Canada, China, Europe, Hong Kong, Israel, India, Mexico, and Taiwan. With the exception of the 596 patent, which the USPTO has determined is entitled to 923 days of patent term adjustment, we expect any U.S. and foreign patents in this patent family to expire in November 2028. In view of the USPTO determination that the 596 patent is entitled to 923 days of patent term adjustment, we expect the 596 patent to expire in June 2031.

It is possible, assuming that plazomicin achieves regulatory approval and depending upon the date of any such approval, that the term of the 596 patent may be extended up to a maximum of five additional years under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, also referred to as the Hatch-Waxman Act. Patent term extension also may be available in certain foreign countries upon regulatory approval.

Antipseudomonal LpxC Inhibitor

Our patent portfolio for antipseudomonal LpxC inhibitor compounds is comprised of seven distinct patent families. Six of these patent families are Achaogen-owned, and one is in-licensed from UW and co-owned by UW with Novartis Corp.

The first of these Achaogen-owned patent families is directed to a chemical genus that encompasses LpxC inhibitor compounds, including ACHN-975, pharmaceutical compositions containing a compound encompassed within the chemical genus and methods of using a compound encompassed within the chemical genus in the treatment of bacterial infections. As of January 31, 2014, this patent family included patent applications pending in the United States (Application Serial No. 12/635,551, filed December 10, 2009), Canada, China, Europe, Hong Kong, India, Japan, and Taiwan. We expect any U.S. and foreign patents granted in this patent family to expire in June 2028.

The second of these Achaogen-owned patent families is directed to ACHN-975 as a composition of matter and structural analogs thereof, pharmaceutical compositions containing ACHN-975 or analogs thereof, and methods of using ACHN-975 or analogs thereof in the treatment of bacterial infections. As of January 31, 2014, this patent family included applications pending in the United States (Application Serial No. 13/289,209, filed November 4, 2011), Argentina, Australia, Brazil, Canada, China, Eurasia, Europe, Israel, India, Japan, Korea, Mexico, New Zealand, Singapore, South Africa, Taiwan, and Venezuela. We expect any U.S. and foreign patents granted in this patent family to expire in November 2031.

The third of these Achaogen-owned patent families also is directed to a chemical genus that encompasses LpxC inhibitor compounds, but not ACHN-975. As of January 31, 2014, this patent family was comprised of International Patent Application No. PCT/US2013/040350, filed May 9, 2013. We expect any U.S. and foreign patents granted in this patent family to expire in May 2033.

The fourth of these Achaogen-owned patent families also is directed to a chemical genus that encompasses LpxC inhibitor compounds, but not ACHN-975. As of January 31, 2014, this patent family was comprised of International Patent Application No. PCT/US2013/040571, filed May 10, 2013. We expect any U.S. and foreign patents granted in this patent family to expire in May 2033.

The fifth and sixth of these Achaogen-owned patent families each is directed to a chemical genus that encompasses LpxC inhibitor compounds, but not ACHN-975. As of January 31, 2014, each of these two patent families was comprised of a pending U.S. provisional patent application. We expect any U.S. and foreign patents granted in these patent families to expire in 2034.

Table of Contents

Index to Financial Statements

As of January 31, 2014, the patent family in-licensed from UW included five issued U.S. patents, two of which (U.S. Patent Nos. 7,989,660 and 8,153,843) we believe may cover ACHN-975 and analogs thereof as a composition of matter. In addition, this patent family includes corresponding foreign patents and patent applications in Australia, Canada, China, Eurasia, Europe, Hong Kong, Indonesia, Israel, India, Japan, Korea, Mexico, the Philippines, Singapore, and South Africa. We believe that certain of these corresponding foreign patents and patent applications may cover ACHN-975 as a composition of matter and that certain of them do not. We expect any U.S. and foreign patents granted in this patent family to expire in January 2024.

If we are successful in developing and obtaining regulatory approval of an antipseudomonal LpxC inhibitor, the term of one U.S. patent issuing from one of our Achaogen-owned patent application families that covers such approved product may be eligible for up to five years of patent term extension under the provisions of the Hatch-Waxman Act. Patent term extension also may be available in certain foreign jurisdictions upon regulatory approval.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We seek to protect our proprietary data and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and partners. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Trade secrets and know-how can be difficult to protect. Consequently, we anticipate that trade secrets and know-how will, over time, be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from academic to industry scientific positions.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with appropriate federal, state, local and foreign statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA s refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA s good laboratory practice, or GLP, regulations;

submission to the FDA of an IND which must become effective before human clinical trials may begin;

Table of Contents

Index to Financial Statements

approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;

performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug product for each indication;

submission to the FDA of an NDA;

satisfactory completion of an FDA advisory committee review, if applicable;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity; and

FDA review and approval of the NDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. To date, we have submitted INDs to the FDA for plazomicin and ACHN-975, which were filed in 2008 and 2012, respectively.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Table of Contents

Index to Financial Statements

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients.

Special Protocol Assessment

The SPA process is designed to facilitate the FDA s review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a drug product s efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor s questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request.

The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions, or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of filing of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a filing decision.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Table of Contents

Index to Financial Statements

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product s continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

The FDA generally accepts data from foreign clinical trials in support of an NDA if the trials were conducted under an IND. If a foreign clinical trial is not conducted under an IND, the FDA nevertheless may accept the data in support of an NDA if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data through an on-site inspection, if deemed necessary. Although the FDA generally requests that marketing applications be supported by some data from domestic clinical studies, the FDA may accept foreign data as the sole basis for marketing approval if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies were performed by clinical investigators with recognized competence, and (3) the data may be considered valid without the need for an on-site inspection or, if the FDA considers the inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA s satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Table of Contents

Index to Financial Statements

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need, or that the drug qualifies as a qualified infectious disease product under the recently enacted GAIN Act. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. We have received fast track designation from the FDA for plazomicin.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten month review periods are measured from the filing date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, passed in July 2012, a sponsor can request designation of a product candidate as a breakthrough therapy. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically

Table of Contents

Index to Financial Statements

significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for plazomicin as appropriate.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product s safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the

Table of Contents

Index to Financial Statements

approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Exclusivity and Approval of Competing Products

Hatch-Waxman Exclusivity

Market and data exclusivity provisions under the FDCA can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the activity of the drug substance. We believe that our product candidates are new chemical entities. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company that references the previously approved drug. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. For drug products that contain an antibiotic ingredient approved prior to 1997, the statute imposes certain limitations on the award of non-patent exclusivity. However, we do not believe these limitations would apply to any of our investigational antibiotics.

Qualified Infectious Disease Product Exclusivity

Under the GAIN Act provisions of FDASIA, which was signed into law in July 2012, the FDA may designate a product as a qualified infectious disease product. In order to receive this designation, a drug must qualify as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (2) a so-called qualifying pathogen found on a list of potentially dangerous, drug-resistant organisms to be established and maintained by the FDA under the new law. A sponsor must request such designation before submitting a marketing application. We expect to request qualified infectious disease product designations for our product candidates prior to submitting a marketing application for such product candidates, as appropriate.

Upon approving an application for a qualified infectious disease product, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded, such as a five-year exclusivity period awarded for a new molecular entity. This extension is in addition to any pediatric exclusivity extension awarded, and the extension will be awarded only to a drug first approved on or after the date of enactment.

Table of Contents

Index to Financial Statements

The GAIN provisions prohibit the grant of an exclusivity extension where the application is a supplement to an application for which an extension is in effect or has expired, is a subsequent application for a specified change to an approved product, or is an application for a product that does not meet the definition of qualified infectious disease product based on the uses for which it is ultimately approved.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. For example, in the European Union, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

To obtain a marketing authorization of a drug in the European Union, we may submit marketing authorization applications, or MAAs, either under the so-called centralized or national authorization procedures.

Centralized Procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the EMA that is valid in all European Union member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee of Medicinal Products for Human Use, or the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

National Authorization Procedures

There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.

Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Table of Contents

Index to Financial Statements

In the European Union, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Regulation of In Vitro Diagnostic Assays

In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Diagnostic tests are classified as medical devices under the FDCA. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and approval of a premarket approval application, or PMA. The FDA classifies all medical devices into one of three classes. Devices deemed to pose lower risk are categorized as either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) pre-market notification requesting clearance of the device for commercial distribution in the United States, unless an exemption applies. Devices deemed by the FDA to pose the greatest risk, such as life sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k)-cleared device are categorized as Class III, requiring a PMA.

To obtain 510(k) clearance for a medical device, a pre-market notification must be submitted to the FDA demonstrating that the proposed device is substantially equivalent to a previously 510(k)-cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA, or the device must be one that has been reclassified from Class III to either Class II or I. The 510(k) clearance process usually takes from three to twelve months from the date the application is submitted and filed with the FDA, but may take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process. After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require pre-market approval. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or a PMA is obtained.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA s satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of

Table of Contents

Index to Financial Statements

both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA s evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

We and our partner, ARK, are developing a companion diagnostic assay for plazomicin and will work together to generate the data required for submission of either a 510(k) submission or a PMA application. We will remain in close contact with the Center for Devices and Radiological Health, or CDRH, at the FDA to ensure that any changes in requirements are incorporated into the development plans. We anticipate that meetings with the FDA with regard to plazomicin as well as the companion diagnostic assay will include representatives from the Center for Drug Evaluation and Research, or CDER, and CDRH to ensure that the drug and device submissions are coordinated to enable the FDA to conduct a parallel review of both submissions. On July 14, 2011, the FDA issued for comment a draft guidance document addressing the development and clearance or approval process for *In vitro* Companion Diagnostic Devices. According to the draft guidance, for novel therapeutic products such as plazomicin, the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic. While this draft guidance is not yet finalized, we believe our programs for the development of our companion diagnostic are consistent with the draft guidance as proposed.

In the European Economic Area, or EEA, *in vitro* medical devices are required to conform with the essential requirements of the EU Directive on *in vitro* diagnostic medical devices (Directive No 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. The data generated for the U.S. registration will be sufficient to satisfy the regulatory requirements for the European Union and other countries.

Fraud and Abuse and Data Privacy and Security Laws and Regulations.

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the biopharmaceutical industry. These laws include anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

Table of Contents

Index to Financial Statements

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes any request or demand for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies marketing of products for unapproved, and thus non-covered, uses. In addition, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, signed into law on March 2010, broadened the reach of both the Anti-Kickback Statute and the criminal healthcare fraud statute by amending the intent requirement such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, PPACA 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 civil False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. PPACA created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals. Applicable manufacturers are also required to report annually to the government certain ownership and investment interests held by physicians and their immediate family members, and payments or other transfers of value to such physician owners and their immediate family members. In addition, certain states require implementation of commercial compliance programs and compliance with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA s privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney s fees and costs associated with pursuing federal civil actions. In addition, state laws govern 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 requirements, thus complicating compliance efforts.

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing

Table of Contents

Index to Financial Statements

requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products or companion diagnostic assay for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payor s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. By way of example, in the United States, the PPACA contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, addressed 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, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies share of sales to federal healthcare programs. 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.

Manufacturing

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on a limited number of third-party contract manufacturers for all of our required raw materials, drug substance, and finished drug product for our preclinical research and clinical trials. We expect that our *in vitro* assay will be manufactured by ARK or another third party supplier. For plazomicin, we source raw materials from various commercial suppliers, primarily located in the People s Republic of China, including sisomicin, the aminoglycoside precursor for plazomicin. Our drug substance is currently manufactured by Hovione Inter Limited and the finished drug product by a U.S. based contract manufacturer. We do not have long-term agreements with these third parties. We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates after they are approved. We currently employ internal resources to manage our manufacturing. If any of our products are approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for the commercial production of those products.

Plazomicin is an organic compound of low molecular weight, commonly referred to as a small molecule. Plazomicin is also considered a semi-synthetic molecule since it is derived from a primary starting material that is a natural product, sisomicin, produced by microbial fermentation. Sisomicin is combined with other starting materials over a series of chemical steps to produce plazomicin. We believe that our use of a synthetic process will enable us to have a cost of manufacturing for plazomicin that is similar to other small molecule antibiotics.

Table of Contents

Index to Financial Statements

Legal Proceedings

We are not currently party to any material legal proceedings.

Facilities

Our headquarters are located in South San Francisco, California, where we lease approximately 35,000 square feet of office and laboratory space. Our lease for the approximately 16,000 square feet of this space that we currently use extends through April 2017, and we have the option to extend the term of the lease for such space through April 2020. We sublease the remaining approximately 19,000 square feet of this space to a subtenant pursuant to a sublease that expires in March 2014 when the lease as to the subleased space will also expire.

Employees

As of December 31, 2013, we had 39 full-time employees, 29 of whom were primarily engaged in research and development activities and 10 of whom were primarily engaged in business development, finance, legal, human resources, facilities, information technology administration and general management. None of our employees is represented by a labor union and we consider our employee relations to be good.

Table of Contents

Index to Financial Statements

MANAGEMENT

The following table sets forth information regarding our current executive officers and directors, with their ages as of December 31, 2013:

Name	Age	Position(s)
Executive Officers		
Kenneth J. Hillan, M.B., Ch.B.	52	President, Chief Executive Officer, Chief Medical Officer and Director
Derek A. Bertocci	59	Senior Vice President and Chief Financial Officer
Becki Filice	53	Senior Vice President, Development Operations and Portfolio Management
Dennis Hom	38	Vice President, Finance and Corporate Development
Christine Murray	53	Vice President, Regulatory Affairs
Non-Employee Directors		
Bryan E. Roberts, Ph.D(2).	46	Chairman of the Board
John C. Doyle	45	Director
Scott M. Rocklage, Ph.D. (1)(3)	59	Director
Camille D. Samuels (1)(2)	42	Director
John W. Smither (1)(2)	60	Director
Christopher T. Walsh, Ph.D(3).	69	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Kenneth J. Hillan, M.B., Ch.B. Dr. Hillan joined Achaogen in April 2011 as Chief Medical Officer and was appointed Chief Executive Officer and a member of our board of directors in October 2011. Prior to joining Achaogen, from August 1994 to April 2011, Dr. Hillan served at Genentech, Inc. (acquired by Roche in 2009), a pharmaceutical company. Dr. Hillan was responsible for numerous successful drug approvals and led the medical and scientific strategies for its Immunology, Tissue Growth and Repair drug portfolio. He served in a number of key leadership positions in research and development, including Senior Vice President Clinical Development, Inflammation, Vice President Immunology, Tissue Growth and Repair (ITGR), Vice President Development Sciences and Vice President Research Operations and Pathology. Dr. Hillan also previously served as Senior Vice President and head of Clinical Development and Product Development Strategy in Asia-Pacific for Roche in Shanghai, China.

Dr. Hillan has an M.B. Ch.B. (Bachelor of Medicine and Surgery) degree from the Faculty of Medicine at the University of Glasgow, U.K. Dr. Hillan is a Fellow of the Royal College of Surgeons (FRCS), and a Fellow of the Royal College of Pathologists (FRCPath). Dr. Hillan has authored dozens of scientific publications and is a named inventor on almost 50 issued patents.

We believe that Dr. Hillan s detailed knowledge of our company and his extensive background in the biotechnology industry, including his roles at Genentech, provide a critical contribution to our board of directors.

Derek A. Bertocci. Mr. Bertocci has served as our Senior Vice President and Chief Financial Officer since February 2014. Prior to joining Achaogen, Mr. Bertocci was Senior Vice President and Chief Financial Officer of Accuray Incorporated, a publicly traded radiation oncology company, from January 2009 to September 2013. From October 2006 through December 2008, Mr. Bertocci served as the Chief Financial Officer of BioForm Medical, Inc., a publicly traded medical aesthetics company. From June 2005 to July 2006, he was Chief

Table of Contents

Index to Financial Statements

Financial Officer of Laserscope, a publicly traded provider of lasers and fiber optic devices for urology and aesthetic surgery. Prior to that, Mr. Bertocci spent a number of years in various roles at VISX Incorporated, a publicly traded provider of systems for laser vision correction surgery, including as Chief Financial Officer from March 2004 to May 2005 and Vice President and Controller from 1998 to March 2004. Mr. Bertocci holds a B.A. from Stanford University and an M.B.A. from the University of Southern California. Mr. Bertocci is also a Certified Public Accountant (inactive).

Becki Filice. Ms. Filice has served as our Senior Vice President, Development Operations and Portfolio Management since November 2012. In this role, she has responsibility for development sciences, clinical operations, biometrics, CMC, project management and human resources. Ms. Filice previously served as our Vice President, Development Operations and Portfolio Management from May 2011 to October 2012. Prior to joining Achaogen, Ms. Filice worked at Genentech, Inc. for 15 years. From June 2009 to April 2011, she held the position of Senior Director, Project Excellence in Global Development. From January 2007 to May 2009, she held the position of Senior Director, Project Portfolio Management in Product Development. Prior to that, she held a number of leadership roles at Genentech, Inc. from March 1996 to December 2006, in the areas of Clinical Data Management and Clinical Operations, and also served as Project Team Leader for both the Avastin® and Nutropin AQ® products. Earlier in her career, Ms. Filice held management positions in clinical research with Ligand Pharmaceuticals Inc. and Syntex, Inc. She started her career as a clinical microbiologist at El Camino Hospital in Mountain View, California. Ms. Filice has a B.A. in Microbiology from University of California, Davis, and an MBA from Santa Clara University, California. She also holds a Project Management Certification from the Pharmaceutical Education and Research Institute and has served as a faculty member of the American Course on Drug Development and Regulatory Sciences (ACDRS).

Dennis Hom. Mr. Hom joined Achaogen in January 2013 as our Vice President, Finance and Corporate Development. From April 2011 to April 2012, Mr. Hom was Executive Director, Corporate Development at Amgen Inc., a biotechnology company. From July 2005 to March 2011, Mr. Hom held various positions in mergers and acquisitions, business development and licensing and sales at Novartis, a pharmaceutical and healthcare products company. Prior to Novartis, Mr. Hom worked in investment banking at a number of firms, including six years at J.P. Morgan and predecessor firm Hambrecht & Quist. Mr. Hom holds a B.S. in Biology from the Massachusetts Institute of Technology. Mr. Hom will be departing his employment with Achaogen effective March 31, 2014.

Christine Murray. Ms. Murray has served as our Vice President, Regulatory Affairs since October 2012. Ms. Murray joined Achaogen in August 2011 as our Senior Director, Regulatory Affairs and Quality Assurance. Ms. Murray has more than 20 years industry experience in global regulatory affairs and drug development gained in both large pharmaceutical and small biotech companies. From June 2008 to July 2011, Ms. Murray was Senior Director, Regulatory Affairs at Alexza Pharmaceuticals, Inc., a specialty pharmaceutical company, where she was responsible for global filing strategies and regulatory agency interactions. From March 2004 to April 2008, Ms. Murray held positions of Director and then Senior Director in the Global Regulatory Affairs department of Gilead Sciences, Inc., a global biotechnology company, where she led regulatory submissions, medical writing and regulatory operations teams. Prior to Gilead, Ms. Murray was an independent regulatory affairs consultant in the U.K., specializing in providing global regulatory and filing strategies. She has been involved in a wide range of regulatory affairs activities from investigational new drug filings to global marketing approvals across a variety of products in the infectious diseases, respiratory, psychiatry and neurology therapeutic areas. Ms. Murray started her career in regulatory affairs at Smithkline Beecham Pharmaceuticals after earlier positions as a clinical biochemist at the Western General Hospital in Edinburgh and Yorkhill Hospital in Glasgow. Ms. Murray has a B.S. in Biochemistry from the University of Liverpool in the U.K., a M.S. degree in Clinical Biochemistry from the University of Newcastle-upon-Tyne in the U.K., and a Regulatory Affairs certification from the University of California, Santa Cruz. She also holds the Regulatory Affairs Certification (U.S.).

Table of Contents

Index to Financial Statements

Directors

Bryan E. Roberts, Ph.D. Dr. Roberts has served on our board of directors since August 2004, and he has served as our Chairman since December 2009. Dr. Roberts joined Venrock, a venture capital investment firm, in 1997, where he serves as Partner. From 1989 to 1992, Dr. Roberts worked in the corporate finance department of Kidder, Peabody & Co., a brokerage company. Dr. Roberts is currently on the board of directors of two publicly traded companies: Zeltiq Aesthetics, a medical technology company, and Ironwood Pharmaceuticals, a pharmaceutical company, where Dr. Roberts serves as Chairman. He also serves on the board of directors of several private companies and previously served on the board of directors of publicly traded Athenahealth, Inc., XenoPort, Inc., and Sirna Therapeutics, Inc. He has a B.A. in Chemistry from Dartmouth College and a Ph.D. in Chemistry and Chemical Biology from Harvard University.

Dr. Roberts brings to our board of directors substantial experience in the life sciences industry, having served on the board of directors of several private and public companies. Dr. Roberts experiences with facilitating the growth of healthcare and biotechnology companies, together with his historical perspective on our company, make him especially qualified to serve on our board of directors as we transition to becoming a public company.

John C. Doyle. Mr. Doyle has served as a member of our board of directors since November 2012. Mr. Doyle joined Castlight Health, a healthcare information company, as Chief Financial Officer in November 2012, and leads the finance, human resources, legal, and corporate development teams. Previously, Mr. Doyle served as our Chief Operating Officer from August 2009 to November 2009 and from February 2011 to November 2012, and as our Chief Financial Officer from November 2009 to February 2011. At Achaogen, Mr. Doyle managed business development, corporate finance, information technology, and business strategy. Prior to joining Achaogen, Mr. Doyle was Vice President of Finance and Corporate Planning at Genentech, Inc., from 2007 to 2009. Mr. Doyle is a member of the 2012 class of Henry Crown Fellows at the Aspen Institute. He has a B.S. in Business Administration from California Polytechnic State University, San Luis Obispo and an M.B.A. from the University of California, Berkeley.

Mr. Doyle brings to our board of directors his deep experience in operational and strategic planning, as well as general executive and leadership expertise, in the pharmaceuticals industry.

Scott M. Rocklage, Ph.D. Dr. Rocklage has served on our board of directors since August 2004. Dr. Rocklage joined 5AM Ventures in 2003 as a Venture Partner and became a Managing Partner in 2004. Dr. Rocklage has over 25 years of healthcare management experience with strategic leadership responsibilities that involved obtaining FDA approval of three NDAs (Ominscan , Teslascan® and Cubicin®). Dr. Rocklage previously served as Chairman and Chief Executive Officer of Cubist Pharmaceuticals, Inc., President and Chief Executive Officer of Nycomed Salutar, and President, Chief Executive Officer and Chairman of Nycomed Interventional. Dr. Rocklage has also held various research and development positions at Salutar and Catalytica. Dr. Rocklage currently serves as Chairman of the Board of Relypsa, Inc., a publicly traded biotechnology company, and of privately held Rennovia, Inc., Kinestral Technologies, Inc., Novira Therapeutics, Inc. and K2 Therapeutics as well as on the board of directors of privately held Pulmatrix, Inc. and Epirus Biopharmaceuticals, Inc. and the Board of Associates at the Whitehead Institute. Dr. Rocklage was formerly Executive Chairman of Ilypsa (acquired by Amgen), Miikana (acquired by EntreMed) and Semprus (acquired by Teleflex). Dr. Rocklage has a B.S. in Chemistry from the University of California, Berkeley and a Ph.D. in Chemistry from the Massachusetts Institute of Technology.

Dr. Rocklage brings to our board of directors his extensive healthcare management experience, scientific background and strategic leadership track record.

Camille D. Samuels. Ms. Samuels has served as a member of our board of directors since August 2004. Ms. Samuels was previously a Managing Director at Versant Ventures, which she joined in 2000. Prior to joining Versant Ventures, Ms. Samuels held business development and strategic marketing roles at Tularik Inc. (acquired by Amgen) and Genzyme (acquired by Sanofi). She also worked as a management consultant to healthcare and

Table of Contents

Index to Financial Statements

biotech companies at LEK Consulting. Ms. Samuels also serves on the board of directors of KYTHERA Biopharmaceuticals, a publicly traded biotechnology company, and of privately held Carmenta Biosciences, and previously served on the board of directors of many privately held biotechnology companies including Novacardia (acquired by Merck), ParAllele (acquired by Affymetrix), and Transcept Pharmaceuticals, Inc. Ms. Samuels has a B.A. in Biology from Duke University and an M.B.A. from Harvard Business School.

Ms. Samuels brings to our board of directors substantial experience as a venture capitalist both generally and in the life sciences industry, having served on the boards of several private and public companies, as well as relevant strategic and operational experience.

John W. Smither has served on our board of directors since December 2013. Since November 2007, Mr. Smither has been Chief Financial Officer of KYTHERA Biopharmaceuticals, Inc., a publicly traded biotechnology company. From 1998 to 2007, Mr. Smither held various positions at Amgen Inc., a publicly traded biotechnology company, including Executive Director of Corporate Accounting, Vice President of Finance and Administration of Amgen s European Division, and Head of Internal Audit. Prior to joining Amgen, Mr. Smither served as Audit Partner at Ernst & Young LLP, a public accounting firm, and as the Chief Financial Officer of several early stage companies. Mr. Smither has a B.S. in Business Administration from California State University, Los Angeles. Mr. Smither is a Certified Public Accountant (inactive) and a member of the American Institute of Certified Public Accountants, the California Society of Certified Public Accountants and Financial Executives International.

Mr. Smither brings to our board of directors his substantive expertise in finance and accounting, and his extensive experience in the biotechnology industry.

Christopher T. Walsh, Ph.D. Dr. Walsh has served on our board of directors since October 2008. Dr. Walsh has been the Hamilton Kuhn Professor of Biological Chemistry and Molecular Pharmacology at Harvard Medical School since 1991 and formerly was president of the Dana-Farber Cancer Institute from 1992 to 1995 and chairman of the Department of Biological Chemistry and Molecular Pharmacology at Harvard Medical School from 1987 to 1995. He has performed extensive research in enzyme stereochemistry, reaction mechanisms and the mechanisms of action of anti-infective and immunosuppressive agents. Dr. Walsh serves on the Scientific Advisory Board for LS9, Inc., Epizyme Corporation, Verastem, Inc., Hua Medicine, and Abide Therapeutics. Dr. Walsh is also a member of the board of directors of Ironwood Pharmaceuticals, Inc., a publicly traded pharmaceuticals company, and Proteostasis Therapeutics, Inc., a privately held biotechnology company. Dr. Walsh has an A.B. in Biology from Harvard University and a Ph.D. in Life Sciences from The Rockefeller University, New York.

Dr. Walsh brings to our board of directors his extensive expertise gained as a scientist at preeminent research institutions and as a director and scientific advisor to numerous life sciences and pharmaceutical companies.

Board Composition

In accordance with our amended and restated certificate of incorporation to take effect following the consummation of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election. After the consummation of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Dr. Rocklage, Ms. Samuels, and Mr. Smither, and their terms will expire at the annual meeting of stockholders to be held in 2015;
- the Class II directors will be Drs. Hillan and Walsh, and their terms will expire at the annual meeting of stockholders to be held in 2016; and
- the Class III directors will be Mr. Doyle and Dr. Roberts, and their terms will expire at the annual meeting of stockholders to be held in 2017.

126

Table of Contents

Index to Financial Statements

Our amended and restated certificate of incorporation will provide that the number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control at our company.

Voting Arrangements

Pursuant to an amended and restated voting agreement, as amended, that we entered into with certain holders of our common stock and certain holders of our convertible preferred stock:

- a majority-in-interest of the Series A convertible preferred stock held by the holders party to such agreement has the right to designate two directors for election to our board of directors, and has selected Dr. Rocklage and Ms. Samuels as such directors;
- a majority-in-interest of the Series B convertible preferred stock held by the holders party to such agreement has the right to designate one director for election to our board of directors, and has selected Dr. Roberts as such director;
- a majority-in-interest of the Series C convertible preferred stock held by the holders party to such agreement has the right to designate one director for election to our board of directors, which seat is currently vacant;
- a majority of the directors comprising our board of directors has the right to designate two directors for election to our board of directors, and has designated Mr. Doyle and Dr. Walsh as such directors;
- a majority-in-interest of the holders of our common stock has the right to designate one director for election to our board of directors, which seat is currently vacant; and
- our then-incumbent Chief Executive Officer has the right to be nominated to serve on our board of directors.

The holders of our common stock and convertible preferred stock who are parties to the amended and restated voting agreement, as amended, are obligated to vote for such designees. The provisions of this voting agreement will terminate upon the consummation of this offering and there will be no further contractual obligations regarding the election of our directors. Our directors hold office until their successors have been elected and qualified or appointed, or the earlier of their death, resignation or removal.

Director Independence

Our common stock has been approved for listing on The NASDAQ Global Market. Under the rules of The NASDAQ Stock Market LLC, or NASDAQ, independent directors must comprise a majority of a listed company s board of directors within twelve months from the date of listing. In addition, NASDAQ rules require that, subject to specified exceptions, each member of a listed company s audit, compensation and nominating and governance committees be independent. Audit committee members must also satisfy additional independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, and in NASDAQ rule 5605(c)(2)(A). Under NASDAQ rules, a director will only qualify as an independent director if, in the opinion of that company s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

127

Table of Contents

Index to Financial Statements

In January 2014, our board of directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that none of our directors, other than Dr. Hillan due to his employment with the Company and Mr. Doyle due to his past employment as an executive officer of the Company, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is independent as that term is defined under NASDAQ rules. Our board of directors also determined that Dr. Rocklage, Ms. Samuels, and Mr. Smither, who are members of our audit committee, Dr. Roberts, Ms. Samuels, and Mr. Smither, who comprise our compensation committee, and Drs. Rocklage and Walsh, who will comprise our nominating and governance committee, satisfy the independence standards for those committees established by applicable SEC rules and NASDAQ rules. In making this determination, our board of directors considered the relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Diversity

Upon completion of our initial public offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, will take into account many factors, including the following:

- diversity of personal and professional background, perspective and experience;
- personal and professional integrity, ethics and values;
- experience in corporate management, operations or finance, such as serving as an officer or former officer of a publicly held company, and a general understanding of marketing, finance and other elements relevant to the success of a publicly-traded company in today s business environment;
- experience relevant to our industry and with relevant social policy concerns;
- experience as a board member or executive officer of another publicly held company;
- relevant academic expertise or other proficiency in an area of our operations;
- practical and mature business judgment, including ability to make independent analytical inquiries;
- promotion of a diversity of business or career experience relevant to our success; and
- any other relevant qualifications, attributes or skills.

Currently, our board of directors evaluates, and following the completion of our initial public offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Board Committees

Our board of directors has established an audit committee and a compensation committee and, intends to establish a nominating and corporate governance committee prior to the completion of this offering. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below.

Table of Contents

Index to Financial Statements

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm s qualifications, independence and performance;
- determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and the audit fee;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible audit and non-audit services;
- monitors the rotation of partners of the independent registered public accounting firm on our engagement team as required by law;
- is responsible for reviewing our financial statements and our management s discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- reviews our critical accounting policies and estimates;
- reviews related party transactions; and
- annually reviews the audit committee charter and the audit committee s performance.

The current members of our audit committee are Dr. Rocklage, Ms. Samuels and Mr. Smither. Mr. Smither serves as the chairman of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and NASDAQ. Our board of directors has determined that Mr. Smither is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable NASDAQ rules and regulations. Under the rules of the SEC and NASDAQ, members of the audit committee must also meet heightened independence standards. Our board has determined that each of the members of the audit committee meet these heightened independence standards. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and NASDAQ.

Compensation Committee

Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. The compensation committee reviews and approves corporate goals and objectives relevant to compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives, and sets the compensation of these officers, other than the Chief Executive Officer, based on such evaluations. The board of directors shall retain the authority to determine and approve, upon the recommendation of the compensation committee, the compensation of the Chief Executive Officer, unless such authority has been delegated to the compensation committee. The compensation committee also approves grants of stock options and other awards under our stock plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance of the compensation committee with its charter. The current members of our compensation committee are Dr. Roberts, Ms. Samuels, and Mr. Smither. Ms. Samuels serves as the chairman of the committee. Each of the members of our compensation committee is an independent, outside and non-employee director under the applicable rules and regulations of the SEC, NASDAQ and the Internal Revenue Code of 1986, as amended, relating to compensation committee independence. The compensation committee operates under a written charter that satisfies the applicable standards of the SEC and NASDAQ.

Table of Contents

Index to Financial Statements

Nominating and Corporate Governance Committee

Upon completion of this offering, the nominating and corporate governance committee will be responsible for making recommendations to our board of directors regarding candidates for directorships and composition and organization of our board of directors. In addition, the nominating and corporate governance committee will be responsible for overseeing our corporate governance policies and reporting and making recommendations to our board of directors concerning governance matters. The members of our nominating and corporate governance committee will be Drs. Rocklage and Walsh. Dr. Rocklage will serve as the chairman of the committee. Each of the members of our nominating and corporate governance committee will be an independent director under the applicable rules and regulations of the SEC and NASDAQ relating to nominating and corporate governance committee independence. The nominating and corporate governance committee will operate under a written charter.

There are no family relationships among any of our directors or executive officers.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2013, Ms. Samuels served as the sole member of the compensation committee. The compensation committee was not formally involved in the determination of executive officer compensation during the fiscal year ended December 31, 2013, which was instead determined by the full board of directors. Dr. Hillan and Mr. Hom participated in deliberations by the board of directors with respect to executive officer compensation during the fiscal year ended December 31, 2013, but neither were present when the Board approved such executive officer compensation. None of our executive officers currently serves, or has served during the last completed three fiscal years, as a member of the board of directors or compensation committee of any other entity that has or had one or more executive officers serving as a member of our board of directors or compensation committee.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a new code of business conduct and ethics that applies to all of our employees, officers, directors and consultants, including those officers responsible for financial reporting. Following the completion of this offering, the code of business conduct and ethics will be available on our website at www.achaogen.com. We expect that any amendments to the code, or any waivers of its requirements for which disclosure is required, will be disclosed on our website. The information contained on or accessible through our website is not a part of this prospectus.

Table of Contents

Index to Financial Statements

EXECUTIVE AND DIRECTOR COMPENSATION

The following is a discussion and analysis of compensation arrangements of our named executive officers, or NEOs. This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an emerging growth company as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

We seek to ensure that the total compensation paid to our executive officers is reasonable and competitive. Compensation of our executives is structured around the achievement of individual performance and near-term corporate targets as well as long-term business objectives.

Our NEOs for 2013 were as follows:

Kenneth J. Hillan, M.B., Ch.B., President and Chief Executive Officer;

Becki Filice, Senior Vice President, Development Operations and Portfolio Management; and

Dennis Hom, Vice President, Finance and Corporate Development.

Summary Compensation Table

The following table sets forth total compensation paid to our named executive officers for the years ended December 31, 2013 and December 31, 2012.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards(1) ($)	Non-Equity Incentive Plan Compensation(2) ($)	All Other Compensation(3) ($)	Total ($)
Kenneth J. Hillan, M.B., Ch.B.,	2013	367,200				7,650	374,850
President and Chief Executive Officer	2012	360,000		965,541	126,000		1,451,541
Becki Filice,	2013	285,600				7,650	293,250
Senior Vice President, Development Operations and Portfolio Management(4)	2012	271,667		227,617	70,000	7,500	576,784
Dennis Hom,	2013	248,106		403,440		7,443	658,989
Vice President, Finance and Corporate Development							

(1) For the option awards column, amounts shown represent the grant date fair value of stock awards and options granted during 2012 or 2013, as applicable, as calculated in accordance with ASC Topic 718. See footnote 10 of the financial statements included in this prospectus for the assumptions used in calculating this amount.

(2) The amounts reported in the Non-Equity Incentive Plan Compensation column represent the annual cash performance-based bonuses earned by our NEOs pursuant to the achievement of certain Company and individual performance objectives. The amounts listed for 2012 were paid to the named executive officers in early 2013. For Ms. Filice, the amount represents the payment of her performance bonus with a pro rata adjustment to reflect her promotion to Senior Vice President in November 2012. Annual cash performance-based bonuses for our NEOs for 2013 have not yet been determined. Please see the descriptions of the annual performance bonuses in Narrative to Summary Compensation Table and Outstanding Equity Awards at 2013 Fiscal Year End *Terms*

and Conditions of Annual Bonuses below.

(3) The amounts reported in the All Other Compensation column constitute the Company s matching contribution under its 401(k) plan.

(4) Ms. Filice was promoted to our Senior Vice President in November 2012. For more information, please see the descriptions of Ms. Filice s employment with us in Narrative to Summary Compensation Table and Outstanding Equity Awards at 2013 Fiscal Year End *Terms and Conditions of Employment Agreements with our NEOs* below.

Table of Contents

Index to Financial Statements

Outstanding Equity Awards at 2013 Fiscal Year End

The following table lists all outstanding equity awards held by our NEOs as of December 31, 2013.

		Option Awards			
Name	Vesting Commencement Date(1)	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Kenneth J. Hillan, M.B., Ch.B.	4/18/2011(2)	132,727		6.93	6/7/2021
	4/18/2011(3)	44,545		6.93	6/7/2021
	4/18/2011(4)	22,272		6.93	6/22/2021
	3/8/2012	132,763		7.26	3/8/2022
	3/8/2012(5)	100,600		7.26	3/8/2022
Becki Filice	5/23/2011(6)	17,613	9,659	6.93	6/7/2021
	9/14/2011(7)	1,585	1,233	7.26	9/14/2021
	3/8/2012	31,600		7.26	3/8/2022
	3/8/2012(8)	33,218		7.26	3/8/2022
Dennis Hom	1/3/2013(2)	71,311		4.73	6/10/2023
	1/3/2013(8)	23,770		4.73	6/10/2023

(1) Except as otherwise noted, options are exercisable immediately, in whole or in part, conditioned upon the NEO entering into a restricted stock purchase agreement with respect to any unvested shares. The shares subject to the options vest and/or are released from the Company s repurchase option, as to 1/48th of the shares subject to such option on each monthly anniversary of the vesting commencement date (and if there is no corresponding day, on the last day of the month), such that all shares will be vested on the fourth anniversary of the vesting commencement date, subject to the holder continuing to provide services to the Company through such vesting date.

(2) The option is exercisable immediately, in whole or in part, conditioned upon the NEO entering into a restricted stock purchase agreement with respect to any unvested shares. The shares subject to the option vest and/or are released from the Company s repurchase option, as to 1/4 of the shares subject to the option on the first anniversary of the vesting commencement date, and thereafter as to 1/48th of the shares subject to such option on each monthly anniversary of the vesting commencement date, such that all shares will be vested on the fourth anniversary of the vesting commencement date, subject to the holder continuing to provide services to the Company through such vesting date.

(3) The option is exercisable immediately, in whole or in part, conditioned upon the NEO entering into a restricted stock purchase agreement with respect to any unvested shares. The shares subject to the option vest and/or are released from the Company s repurchase option, as to 100% of the shares subject to the option on the fourth anniversary of the vesting commencement date, subject to the holder continuing to provide services to the Company through such vesting date.

(4) The option is exercisable immediately, in whole or in part, conditioned upon the NEO entering into a restricted stock purchase agreement with respect to any unvested shares. The shares subject to the option vest and/or are released from the Company s repurchase option, as to 100% of the shares subject to the option on the sixth anniversary of the vesting commencement date, subject to the holder continuing to provide services to the Company through such vesting date.

(5) The option is exercisable immediately, in whole or in part, conditioned upon Dr. Hillan entering into a restricted stock purchase agreement with respect to any unvested shares. The shares subject to the option vest and/or are released from the Company s repurchase option, as to 47,472 of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $33.00 per share, as to 47,472 of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $55.00 per share, and as to 5,656 of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $77.00 per share (in each case, as appropriately adjusted for stock splits, stock dividends, recapitalizations and the like) respectively, subject to Dr. Hillan continuing to provide services to the Company through such vesting date.

(6) The shares subject to the option vest and become exercisable as to 1/4th of the shares subject to the option on the first anniversary of the vesting commencement date, and thereafter as to 1/48th of the shares subject to the option on each monthly anniversary of the vesting commencement date, such that all shares will be vested and exercisable on the fourth anniversary of the vesting commencement date, subject to the holder continuing to provide services to the Company through such vesting date.

(7) The shares subject to the option vest and become exercisable as to 1/48th of the shares subject to the option on each monthly anniversary of the vesting commencement date (and if there is no corresponding day, on the last day of the month), such that all shares will be vested and exercisable on the fourth anniversary of the vesting commencement date, subject to the holder continuing to provide services to the Company through such vesting date.

Table of Contents

Index to Financial Statements

(8) The option is exercisable immediately, in whole or in part, conditioned upon the NEO entering into a restricted stock purchase agreement with respect to any unvested shares. The shares subject to the option vest and/or are released from the Company s repurchase option, as to 1/3rd of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $33.00, $55.00 and $77.00 (in each case, as appropriately adjusted for stock splits, stock dividends, recapitalizations and the like), respectively, subject to the holder continuing to provide services to the Company through such vesting date.

Narrative to Summary Compensation Table and Outstanding Equity Awards at 2013 Fiscal Year End

Terms and Conditions of Employment Agreements with our NEOs

We have entered into agreements with each of the NEOs in connection with his or her employment with us. These agreements set forth the terms and conditions of employment of each named executive officer, including base salary, target annual bonus opportunity and standard employee benefit plan participation. Our board of directors or the compensation committee reviews each NEO s base salary and target bonus opportunity from time to time to ensure compensation adequately reflects the NEO s qualifications, experience, role and responsibilities. For fiscal year 2013, Dr. Hillan s base salary was $367,200, Ms. Filice s base salary was $285,600, and Mr. Hom s base salary was $250,000. In addition, for 2013, Dr. Hillan, Ms. Filice, and Mr. Hom each had an annual bonus target of 35%, 30%, and 25%, respectively, of base salary awarded based on the achievement of certain milestones established by our board of directors. Mr. Hom joined as our Vice President, Finance and Corporate Development on January 3, 2013, so his salary has been, and his bonus will be, pro-rated for the portion of 2013 served. For fiscal year 2012, Dr. Hillan s base salary was $360,000. Ms. Filice s base salary was $270,000 for the first ten months of 2012 and then was $280,000 for the remaining two months of 2012 to reflect Ms. Filice s promotion to Senior Vice President in November 2012. In addition, for 2012, Dr. Hillan had an annual bonus target of 35% of base salary. Ms. Filice s annual bonus target was 25% for the first ten months of 2012 and then was 30% for the remaining two months of 2012 to reflect Ms. Filice s promotion to Senior Vice President. Ms. Filice s bonus target was pro ratably adjusted to reflect her target achievement before and after her promotion. Please see the section below entitled *Terms and Conditions of Annual Bonuses* for a further description of our annual bonus program for our NEOs.

In the event Dr. Hillan s employment is terminated other than the period commencing three months prior to and ending 12 months following a change of control (as defined below), other than (a) for cause (as defined below) or (b) as a result of his death or disability, and he executes and does not revoke a general release of claims in favor of the Company, then (i) Dr. Hillan will receive a severance payment equal to six months of his base salary, payable in six equal monthly installments, and (ii) 25% of Dr. Hillan s then-unvested option grants will immediately vest and become exercisable. In the event Dr. Hillan s employment is terminated within the period commencing three months prior to and ending 12 months following a change of control, other than (a) for cause (as defined below) or (b) as a result of his death or disability, or in the event he resigns for good reason (as defined below) within such period, and, in either case, he executes and does not revoke a general release of claims in favor of the Company, then (i) Dr. Hillan will receive a severance payment equal to his annual base salary, payable in 12 equal monthly installments, and (ii) 50% of Dr. Hillan s then-unvested option grants will immediately vest and become exercisable. Ms. Filice and Mr. Hom do not have any severance or change of control benefits under their employment agreements. Please see the section below entitled *Terms and Conditions of Equity Award Grants* for a description of additional vesting acceleration of each of our NEO s outstanding equity awards upon a change of control.

For purposes of our employment agreement with Dr. Hillan, cause means (i) an act of dishonesty made by Dr. Hillan in connection with his responsibilities as an employee, (ii) Dr. Hillan s conviction of, or plea of nolo contendere to, a felony, (iii) Dr. Hillan s gross misconduct, or (iv) Dr. Hillan s continued substantial violations of his employment duties after he has received a written demand for performance from the Company which specifically sets forth the factual basis for the Company s belief that he has not substantially performed his duties.

For purposes of our employment agreement with Dr. Hillan, good reason means Dr. Hillan s resignation within 30 days following the expiration of the Company cure period (discussed below) following the occurrence

Table of Contents

Index to Financial Statements

of one or more of the following, without Dr. Hillan s express written consent: (i) a material reduction in Dr. Hillan s annual base salary unless such reduction is part of a Company-wide reduction for similarly situated persons where the reduction applied to Dr. Hillan is substantially similar to the reduction for the other similarly situated employees; (ii) the significant reduction of Dr. Hillan s duties or responsibilities relative to his duties or responsibilities in effect immediately prior to such reduction; provided, however, that a reduction in duties or responsibilities solely by virtue of the Company being acquired and made part of a larger entity (as, for example, when the Chief Executive Officer of the Company remains as such for the operations of the Company following a change of control and is not made the Chief Executive Officer of the acquiring corporation) shall not constitute good reason ; or (iii) a material change in the geographic location at which Dr. Hillan must perform services (it being understood that a relocation more than 50 miles is material). Before Dr. Hillan may resign for good reason, (A) Dr. Hillan must provide the Company with written notice within 90 days of the event that he believes constitutes good reason specifically identifying the acts or omissions constituting the grounds for good reason and (B) the Company must have an opportunity within 30 days following delivery of such notice to cure the good reason condition.

For purposes of our employment agreement with Dr. Hillan, change of control means: (i) the acquisition of the Company by another entity by means of any transaction or series of related transactions (including, without limitation, any stock acquisition, reorganization, merger or consolidation but excluding any sale of stock for capital raising purposes) other than a transaction or series of transactions in which the holders of the voting securities of the Company outstanding immediately prior to such transaction continue to retain (either by such voting securities remaining outstanding or by such voting securities being converted into voting securities of the surviving entity or its parent), as a result of shares in the Company held by such holders prior to such transaction, at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent, as applicable, outstanding immediately after such transaction or series of transactions; (ii) a sale, lease or other conveyance of all or substantially all of the assets of the Company; or (iii) any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary.

Terms and Conditions of Annual Bonuses

For 2012 and 2013, all of our NEOs were eligible for performance-based cash incentives pursuant to the achievement of certain performance objectives. The performance goals for these annual performance cash incentives were reviewed and approved by our board of directors. The determination of the amount of bonuses paid to our NEOs generally reflects a number of considerations, including individual performance and financing and research goals.

Target Bonus Opportunity

Each NEO s target bonus opportunity is expressed as a percentage of base salary which can be achieved by meeting corporate goals and may be increased or decreased based on individual performance. For each of our NEOs, their target bonus opportunity is originally set in their offer letters with the Company as described above. Our board of directors or our compensation committee has historically reviewed these target percentages to ensure they are adequate, but does not follow a formula. Instead, our board of directors or our compensation committee has set these rates based on each participating executive s experience in her or his role with the company and the level of responsibility held by each executive, which the board of directors or our compensation committee believe directly correlates to her or his ability to influence corporate results. For fiscal year 2013, our board of directors used a guideline target bonus opportunity of 35% of base salary for Dr. Hillan, 30% of base salary for Ms. Filice, and 25% of base salary for Mr. Hom. For fiscal year 2012, our board of directors used a guideline target bonus opportunity of 35% for Dr. Hillan. Our board of directors used a guideline target bonus opportunity of 25% for Ms. Filice for the first ten months of 2012 and then used 30% for Ms. Filice for the remaining two months of 2012 to reflect Ms. Filice s promotion to Senior Vice President. Ms. Filice s bonus target was pro ratably adjusted to reflect her target achievement before and after her promotion.

Table of Contents

Index to Financial Statements

Performance Goals and Weighting

For determining the performance bonus amounts for our NEOs for 2012 and 2013, our board of directors set certain corporate performance goals, using a mixture of research, clinical, regulatory, government funding, workplace satisfaction and other financing targets. These performance goals were not expected to be attained based on average or below average performance. After determining performance targets, each performance target was given a different weight for determining the overall bonus amount based on the importance to the success of the Company for each performance target. For fiscal year 2013, plazomicin clinical, regulatory, partnering, and government funding targets were weighted at 40%, ACHN-975 clinical and government funding targets were weighted at 20%, additional research targets were weighted at 15%, a financing target was weighted at 15%, and workplace satisfaction targets were weighted at 10%. The financing target can also increase bonus amounts by an additional 15%. For fiscal year 2012, plazomicin clinical, regulatory and government funding targets were weighted at 35%, ACHN-975 clinical and government funding targets were weighted at 25%, research, clinical, regulatory and government funding targets for a subsequently terminated aminoglycoside program were weighted at 15%, additional research targets were weighted at 15% and workplace satisfaction targets were weighted at 10%. An additional financing target for 2012 could have increased or decreased bonus amounts by 20%.

In addition, after considering the corporate performance goals, the board then has the discretion to increase or decrease bonus amounts for each NEO based on individual performance and individual contributions to the Company s success.

Achievement Level

In early 2013, the board of directors established the corporate performance goals and weightings for 2013 described above. For each of these performance goals, the board of directors set a target achievement level. There was no minimum or maximum achievement for each performance target; instead the board weighs the achievement, partial achievement or non-achievement for each performance target when deciding the overall achievement level. The board of directors has not yet determined target achievement for 2013 or determined bonus amounts for 2013.

In early 2012, the board of directors established the corporate performance goals and weightings for 2012 described above. For each of these performance goals, the board of directors set a target achievement level. There was no minimum or maximum achievement for each performance target; instead the board weighs the achievement, partial achievement or non-achievement for each performance target when deciding the overall achievement level. In early 2013, the board of directors reviewed our 2012 performance with respect to determining bonuses to executive officers. The board of directors determined the target achievement at 85%, as detailed in the below table:

Performance Goal	Target Achievement Percentage	Actual 2012 Achievement Percentage
Plazomicin Clinical, Regulatory and Government Funding Targets	35%	35%
ACHN-975 Clinical and Government Funding Targets	25%	10%
Research, Clinical, Regulatory and Government Funding Targets for Subsequently Terminated Aminoglycoside Program	15%	5%
Additional Research Targets	15%	15%
Workplace Satisfaction Targets	10%	10%
Financing Targets	+/-20%	+10%
Total	100%(+/-20%)	85%

Following its review and determinations of the target achievement for 2012, the board of directors awarded cash bonuses to the NEOs of 100% of their target bonus opportunities, increasing each NEO s bonus payment compared to the 85% achievement of the corporate performance goals as a result of each executive s outstanding individual performance and additional responsibilities undertaken in 2012, particularly the positive reception of our

Table of Contents

Index to Financial Statements

planned plazomicin development program from the FDA and BARDA and successfully managing the Company through a staff reduction. The NEO s 2012 bonuses are set forth in the Summary Compensation Table above.

Terms and Conditions of Equity Award Grants

Dr. Hillan and Ms. Filice received options to purchase our common stock in fiscal year 2012. Mr. Hom received options to purchase our common stock in fiscal year 2013. The table above entitled Outstanding Equity Awards at 2013 Fiscal Year End describes the material terms of other option awards made in past fiscal years to our NEOs.

In June 2013, our board of directors granted two separate option awards to Mr. Hom which were exercisable immediately with an exercise price of $4.73 per share, which the board determined was the fair market value on the date of grant. The first option award of 71,311 shares granted to Mr. Hom vests as to 1/4th of the shares subject to the option on the first anniversary of the vesting commencement date of January 3, 2013, and thereafter as to 1/48th of the shares subject to such option on each monthly anniversary of the vesting commencement date such that 100% of the shares subject to the option will be vested and exercisable on the fourth anniversary of the vesting commencement date, subject to Mr. Hom continuing to provide services to the Company through such vesting date. The second option award of 23,770 shares granted to Mr. Hom vests as to 1/3rd of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $33.00, $55.00 and $77.00 (in each case, as appropriately adjusted for stock splits, stock dividends, recapitalizations and the like), respectively, subject to Mr. Hom continuing to provide services to the Company through such vesting date. In January 2014, in connection with Mr. Hom s planned departure from the Company on March 31,2014, we modified the option awards granted to Mr. Hom to permit him to exercise such awards through September 30, 2014 to the extent vested as of March 31, 2014.

In March 2012, our board of directors granted two separate option awards to each of Dr. Hillan and Ms. Filice, which were exercisable immediately, with an exercise price of $7.26 per share, which the board determined was the fair market value on the date of grant. The first option awards of 132,763 shares and 31,600 shares granted to Dr. Hillan and Ms. Filice, respectively, vest as to 1/48th of the shares subject to such option on each monthly anniversary of the vesting commencement date (and if there is no corresponding day, on the last day of the month) such that 100% of the shares subject to the option will be vested and exercisable on the fourth anniversary of the vesting commencement date, subject to the holder continuing to provide services to the Company through such vesting date. The second option awards of 142,418 shares and 33,218 shares granted to Dr. Hillan and Ms. Filice, respectively, vest as to 1/3rd of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $33.00, $55.00 and $77.00 (in each case, as appropriately adjusted for stock splits, stock dividends, recapitalizations and the like), respectively, subject to the holder continuing to provide services to the Company through such vesting date.

In February 2013, we modified the option award granted to Dr. Hillan in March 2012 to purchase 142,418 shares of our common stock to reduce the number of shares subject to such award by 41,818 shares. As a result of the modification, the option vests as to as to 47,472 of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $33.00 per share, 47,472 of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $55.00 per share, and the remaining 5,656 of the shares subject to the option on the date that the closing trading price of the Company s common stock first reaches or exceeds $77.00 per share (in each case, as appropriately adjusted for stock splits, stock dividends, recapitalizations and the like), respectively, subject to Dr. Hillan continuing to provide services to the Company through such vesting date.

In accordance with our Change in Control Plan effective as of March 8, 2012, in the event of the consummation of a change in control (as defined below) on or prior to December 31, 2014, each option and other equity award granted to our full-time employees who remain employed with the Company immediately prior to the Company s entry into an acquisition agreement, including our NEOs, vests as to 100% of the shares subject to such equity award effective as of immediately prior to the change in control, subject to each such employee

Table of Contents

Index to Financial Statements

executing and not revoking a general release of claims against the Company. There are no other benefits or payments payable under our Change in Control Plan, which will terminate on December 31, 2014 if the Company does not enter into an acquisition agreement prior to that time. For purposes of the Change in Control Plan, change in control means (i) any acquisition of the Company by another entity by means of any transaction or series of related transactions to which the Company or its stockholders is party (including, without limitation, any stock acquisition, reorganization, merger or consolidation, but excluding any sale of stock for capital raising purposes) other than a transaction or series of transactions in which the holders of the voting securities of the Company outstanding immediately prior to such transaction continue to retain (either by such voting securities remaining outstanding or by such voting securities being converted into voting securities of the surviving entity), as a result of shares in the Company held by such holders prior to such transaction, at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such transaction or series of transactions, or (ii) a sale, lease, exclusive license or other conveyance of all or substantially all of the assets of the Company.

Terms and Conditions of 401(k) Plan

Our U.S. eligible employees, including our NEOs, participate in our 401(k) Plan. Enrollment in the 401(k) Plan is automatic for employees who meet eligibility requirements unless they decline participation. Under the 401(k) Plan, we provide matching contributions equal to 50% of employees contribution, up to 6% of annual earnings. The maximum employee contribution to the 401(k) Plan is 100% of an employee s annual eligible compensation, subject to regulatory and plan limitations.

Director Compensation

Prior to the consummation of this offering, we generally did not compensate our non-employee directors for their service on our board of directors, and we did not pay director fees to our directors who are our employees. However, we provide reimbursement to our non-employee directors for their reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors. In addition, in December 2012, we granted an option to purchase 29,545 shares of our common stock to each of our non-employee directors at that time that were not affiliated with one of our venture capital stockholders, which options vest in substantially equal monthly installments over the four years following the date of grant, subject to each such director continuing to be a service provider to us.

Our non-employee directors received no compensation from us during the year ended December 31, 2013. Dr. Hillan received no additional compensation for his service as a director. As of December 31, 2013, Mr. Doyle held options to purchase 88,114 shares of our common stock and Dr. Walsh held options to purchase 43,181 shares of our common stock. No other non-employee director held any options to purchase shares of our common stock or any other equity award as of December 31, 2013.

In January 2014, our board of directors approved a compensation policy for our non-employee directors to be effective in connection with the consummation of this offering, or the Post-IPO Director Compensation Program. Pursuant to the Post-IPO Director Compensation Program, our non-employee directors will receive cash compensation, paid quarterly in arrears, as follows:

Each non-employee director will receive an annual cash retainer in the amount of $35,000 per year.

The Chairman will each receive an additional annual cash retainer in the amount of $27,500 per year.

The chairperson of the audit committee will receive additional annual cash compensation in the amount of $15,000 per year for such chairperson s service on the audit committee. Each non-chairperson member of the audit committee will receive additional annual cash compensation in the amount of $7,500 per year for such member s service on the audit committee.

Table of Contents

Index to Financial Statements

The chairperson of the compensation committee will receive additional annual cash compensation in the amount of $10,000 per year for such chairperson s service on the compensation committee. Each non-chairperson member of the compensation committee will receive additional annual cash compensation in the amount of $5,000 per year for such member s service on the compensation committee.

The chairperson of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $7,000 per year for such chairperson s service on the nominating and corporate governance committee. Each non-chairperson member of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $3,000 per year for such member s service on the nominating and corporate governance committee.

Under the Post-IPO Director Compensation Program, each non-employee director will receive an option to purchase 20,000 shares of our common stock upon the director s initial appointment or election to our board of directors, referred to as the Initial Grant, and an annual option to purchase 10,000 shares of our common stock on the date of each annual stockholder s meeting thereafter, referred to as the Annual Grant. The Initial Grant will vest as to 1/36th of the shares subject to Initial Grant each month following the applicable grant date, subject to continued service through each applicable vesting date. The Annual Grant will vest as to 1/12th of the shares subject to the Annual Grant each month following the applicable grant date, which vesting will accelerate in full on the date of the next annual stockholder s meeting to the extent unvested as of such date, subject to continued service through each applicable vesting date. Upon the pricing of this offering, each non-employee director received an option to purchase 10,000 shares of our common stock at an exercise price per share equal to the initial public offering price set forth on the cover of this prospectus, which option will vest as to 1/12th of the shares subject thereto each month following the date of the pricing of this offering, which vesting will accelerate in full on the date of the next annual stockholder s meeting to the extent unvested as of such date, subject to continued service through each applicable vesting date.

Employee Equity Plans

The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the text of the plans or agreements, which are filed as exhibits to the registration statement.

2014 Equity Incentive Award Plan

We have adopted a 2014 Equity Incentive Award Plan, or the 2014 Plan, which became effective upon the effectiveness of the registration statement to which this prospectus relates. The principal purpose of the 2014 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The material terms of the 2014 Plan are summarized below.

Share Reserve. Under the 2014 Plan, 963,636 shares of our common stock were initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards, deferred stock awards, dividend equivalent awards, stock payment awards, performance awards and other stock-based awards, plus the number of shares remaining available for future awards under our Amended and Restated 2003 Stock Plan, as amended, or the 2003 Plan, as of the effectiveness of the registration statement to which this prospectus relates. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2014 Plan will be increased by (i) the number of shares represented by awards outstanding under our 2003 Plan that are forfeited or lapse unexercised and which following the effective date are not issued under our 2003 Plan and (ii) if approved by our board of directors or the compensation committee of our board of directors, an annual increase on the first day of each fiscal year beginning in 2015 and ending in 2024, equal to the lesser of (A) 4% of the shares of our common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such

Table of Contents

Index to Financial Statements

smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 14,545,454 shares of stock may be issued upon the exercise of incentive stock options.

The following counting provisions will be in effect for the share reserve under the 2014 Plan:

- to the extent that an award terminates, expires or lapses for any reason or an award is settled in cash without the delivery of shares, any shares subject to the award at such time will be available for future grants under the 2014 Plan;
- to the extent shares are tendered or withheld to satisfy the grant, exercise price or tax withholding obligation with respect to any award under the 2014 Plan, such tendered or withheld shares will not be available for future grants under the 2014 Plan;
- to the extent that shares of our common stock are repurchased by us prior to vesting so that shares are returned to us, such shares will be available for future grants under the 2014 Plan;
- the payment of dividend equivalents in cash in conjunction with any outstanding awards will not be counted against the shares available for issuance under the 2014 Plan; and
- to the extent permitted by applicable law or any exchange rule, shares issued in assumption of, or in substitution for, any outstanding awards of any entity acquired in any form of combination by us or any of our subsidiaries will not be counted against the shares available for issuance under the 2014 Plan.

Administration. The compensation committee of our board of directors is expected to administer the 2014 Plan unless our board of directors assumes authority for administration. The compensation committee must consist of at least three members of our board of directors, each of whom is intended to qualify as an outside director within the meaning of Section 162(m) of the Code, a non-employee director for purposes of Rule 16b-3 under the Exchange Act and an independent director within the meaning of the rules of the applicable stock exchange, or other principal securities market on which shares of our common stock are traded. The 2014 Plan provides that the board or compensation committee may delegate its authority to grant awards to employees other than executive officers and certain senior executives of the company to a committee consisting of one or more members of our board of directors or one or more of our officers, other than awards made to our non-employee directors, which must be approved by our full board of directors.

Subject to the terms and conditions of the 2014 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards, and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2014 Plan. The administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2014 Plan. Our board of directors may at any time remove the compensation committee as the administrator and revest in itself the authority to administer the 2014 Plan. The full board of directors will administer the 2014 Plan with respect to awards to non-employee directors.

Eligibility. Options, SARs, restricted stock and all other stock-based and cash-based awards under the 2014 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our subsidiaries. Such awards also may be granted to our directors. Only employees of our company or certain of our subsidiaries may be granted incentive stock options, or ISOs.

Awards. The 2014 Plan provides that the administrator may grant or issue stock options, SARs, restricted stock, restricted stock units, deferred stock, dividend equivalents, performance awards, stock payments and other stock-based and cash-based awards, or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

Nonstatutory Stock Options, or NSOs, will provide for the right to purchase shares of our common stock at a specified price which may not be less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant date, subject to

Table of Contents

Index to Financial Statements

the participant s continued employment or service with us and/or subject to the satisfaction of corporate performance targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that does not exceed ten years.

Incentive Stock Options will be designed in a manner intended to comply with the provisions of Section 422 of the Code and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2014 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.

Restricted Stock may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock, typically, may be forfeited for no consideration or repurchased by us at the original purchase price if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will have the right to receive dividends, if any, prior to the time when the restrictions lapse; however, extraordinary dividends will generally be placed in escrow, and will not be released until restrictions are removed or expire.

Restricted Stock Units may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. Like restricted stock, restricted stock units may not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.

Deferred Stock Awards represent the right to receive shares of our common stock on a future date. Deferred stock may not be sold or otherwise hypothecated or transferred until issued. Deferred stock will not be issued until the deferred stock award has vested, and recipients of deferred stock generally will have no voting or dividend rights prior to the time when the vesting conditions are satisfied and the shares are issued. Deferred stock awards generally will be forfeited, and the underlying shares of deferred stock will not be issued, if the applicable vesting conditions and other restrictions are not met.

Stock Appreciation Rights, or SARs, may be granted in connection with stock options or other awards, or separately. SARs granted in connection with stock options or other awards typically will provide for payments to the holder based upon increases in the price of our common stock over a set exercise price. The exercise price of any SAR granted under the 2014 Plan must be at least 100% of the fair market value of a share of our common stock on the date of grant. Except as required by Section 162(m) of the Code with respect to a SAR intended to qualify as performance-based compensation as described in Section 162(m) of the Code, there are no restrictions specified in the 2014 Plan on the exercise of SARs or the amount of gain realizable therefrom, although restrictions may be imposed by the administrator in the SAR agreements. SARs under the 2014 Plan will be settled in cash or shares of our common stock, or in a combination of both, at the election of the administrator.

Dividend Equivalents represent the value of the dividends, if any, per share paid by us, calculated with reference to the number of shares covered by the award. Dividend equivalents may be settled in cash or shares and at such times as determined by the compensation committee or board of directors, as applicable.

Performance Awards may be granted by the administrator on an individual or group basis. Generally, these awards will be based upon specific performance targets and may be paid in cash or in common stock or in a combination of both. Performance awards may include

phantom stock awards that provide

Table of Contents

Index to Financial Statements

for payments based upon the value of our common stock. Performance awards may also include bonuses that may be granted by the administrator on an individual or group basis and which may be payable in cash or in common stock or in a combination of both.

Stock Payments may be authorized by the administrator in the form of common stock or an option or other right to purchase common stock as part of a deferred compensation or other arrangement in lieu of all or any part of compensation, including bonuses, that would otherwise be payable in cash to the employee, consultant or non-employee director.

Change in Control. In the event of a change in control where the acquirer does not assume or replace awards granted, prior to the consummation of such transaction, awards issued under the 2014 Plan, except for any performance award, will be subject to accelerated vesting such that 100% of such awards will become vested and exercisable or payable, as applicable. The vesting of any performance awards not assumed in a change in control will not be automatically accelerated and will only accelerate to the extent provided in the applicable award agreement. In addition, the administrator will also have complete discretion to structure one or more awards under the 2014 Plan to provide that such awards will become vested and exercisable or payable on an accelerated basis in the event such awards are assumed or replaced with equivalent awards but the individual s service with us or the acquiring entity is subsequently terminated within a designated period following the change in control event. The administrator may also make appropriate adjustments to awards under the 2014 Plan and is authorized to provide for the acceleration, cash-out, termination, assumption, substitution or conversion of such awards in the event of a change in control or certain other unusual or nonrecurring events or transactions.

In the event that, within the 12 month period immediately following a change in control, a participant s services with us are terminated by us for other than cause (as defined in the 2014 Plan) or by such participant for good reason (as defined in the 2014 Plan), then the vesting and, if applicable, exercisability of 100% of the then-unvested shares subject to the outstanding equity awards held by such participant under the 2014 Plan will accelerate effective as of the date of such termination.

Adjustments of Awards. In the event of any stock dividend, stock split, combination or exchange of shares, merger, consolidation, spin-off, recapitalization, distribution of our assets to stockholders (other than normal cash dividends) or any other corporate event affecting the number of outstanding shares of our common stock or the share price of our common stock that would require adjustments to the 2014 Plan or any awards under the 2014 Plan in order to prevent the dilution or enlargement of the potential benefits intended to be made available thereunder, the administrator will make appropriate, proportionate adjustments to:

the aggregate number and type of shares subject to the 2014 Plan;

the number and kind of shares subject to outstanding awards and terms and conditions of outstanding awards (including, without limitation, any applicable performance targets or criteria with respect to such awards); and

the grant or exercise price per share of any outstanding awards under the 2014 Plan.

Amendment and Termination. Our board of directors or the compensation committee (with board approval) may terminate, amend or modify the 2014 Plan at any time and from time to time. However, we must generally obtain stockholder approval:

to increase the number of shares available under the 2014 Plan (other than in connection with certain corporate events, as described above);

to grant options with an exercise price that is below 100% of the fair market value of shares of our common stock on the grant date;

to extend the exercise period for an option beyond ten years from the date of grant; or

to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule).

Table of Contents

Index to Financial Statements

Notwithstanding the foregoing, an option may be amended to reduce the per share exercise price below the per share exercise price of such option on the grant date and options may be granted in exchange for, or in connection with, the cancellation or surrender of options having a higher per share exercise price without receiving additional stockholder approval.

Termination. The board of directors may terminate the 2014 Plan at any time. No incentive stock options may be granted pursuant to the 2014 Plan after the tenth anniversary of the effective date of the 2014 Plan, and no additional annual share increases to the 2014 Plan s aggregate share limit will occur from and after such anniversary. Any award that is outstanding on the termination date of the 2014 Plan will remain in force according to the terms of the 2014 Plan and the applicable award agreement.

We intend to file with the SEC a registration statement on Form S-8 covering the shares of our common stock issuable under the 2014 Plan.

Employee Stock Purchase Plan

We have adopted an Employee Stock Purchase Plan, which we refer to as our ESPP, which became effective upon the effectiveness of the registration statement to which this prospectus relates. The ESPP is designed to allow our eligible employees to purchase shares of our common stock, at semi-annual intervals, with their accumulated payroll deductions. The ESPP is intended to qualify under Section 423 of the Code.

Plan Administration. Subject to the terms and conditions of the ESPP, our compensation committee will administer the ESPP. Our compensation committee can delegate administrative tasks under the ESPP to the services of an agent and/or employees to assist in the administration of the ESPP. The administrator will have the discretionary authority to administer and interpret the ESPP. Interpretations and constructions of the administrator of any provision of the ESPP or of any rights thereunder will be conclusive and binding on all persons. We will bear all expenses and liabilities incurred by the ESPP administrator.

Shares Available Under ESPP. The maximum number of our shares of our common stock which are authorized for sale under the ESPP is equal to the sum of (a) 145,454 shares of common stock and (b), if approved by our board of directors or the compensation committee of our board of directors, an annual increase on the first day of each year beginning in 2015 and ending in 2024, equal to the lesser of (i) one percent (1%) of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by our board of directors; provided, however, no more than 3,181,818 shares of our common stock may be issued under the ESPP. The shares made available for sale under the ESPP may be authorized but unissued shares or reacquired shares reserved for issuance under the ESPP.

Eligible Employees. Employees eligible to participate in the ESPP generally include employees who are employed by us or one of our subsidiaries on the first trading day of an offering period, or the enrollment date. Our employees and any employees of our subsidiaries who customarily work less than five months in a calendar year or are customarily scheduled to work less than 20 hours per week will not be eligible to participate in the ESPP. Finally, an employee who owns (or is deemed to own through attribution) 5% or more of the combined voting power or value of all our classes of stock or of one of our subsidiaries will not be allowed to participate in the ESPP.

Participation. Employees will enroll under the ESPP by completing a payroll deduction form permitting the deduction from their compensation of at least 1% of their compensation but not more than the lesser of 15% of their compensation and $25,000 per offering period. Such payroll deductions may be expressed as either a whole number percentage or a fixed dollar amount and the accumulated deductions will be applied to the purchase of shares on each semi-annual purchase date. However, a participant may not purchase more than 3,000 shares in each offering period, and may not subscribe for more than $25,000 in fair market value of shares our common stock (determined at the time the option is granted) during any calendar year. The ESPP administrator has the authority to change these limitations for any subsequent offering period.

Table of Contents

Index to Financial Statements

Offering. Under the ESPP, participants are offered the option to purchase shares of our common stock at a discount during a series of successive offering periods, which will normally commence on March 1 and September 1 of each year. The initial offering period will commence and end on dates as determined by the ESPP administrator. Unless otherwise determined by the ESPP administrator, each offering period will have a duration of six months. However, in no event may an offering period be longer than 27 months in length.

The option purchase price will be the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the semi-annual purchase date, which will occur on the last trading day of each offering period.

Unless a participant has previously canceled his or her participation in the ESPP before the purchase date, the participant will be deemed to have exercised his or her option in full as of each purchase date. Upon exercise, the participant will purchase the number of whole shares that his or her accumulated payroll deductions will buy at the option purchase price, subject to the participation limitations listed above.

A participant may cancel his or her payroll deduction authorization at any time prior to the end of the offering period. Upon cancellation, the participant will have the option to either (a) receive a refund of the participant s account balance in cash without interest or (b) exercise the participant s option for the current offering period for the maximum number of shares of common stock on the applicable purchase date, with the remaining account balance refunded in cash without interest. Following at least one payroll deduction, a participant may also decrease (but not increase) his or her payroll deduction authorization once during any offering period. If a participant wants to increase or decrease the rate of payroll withholding, he or she may do so effective for the next offering period by submitting a new form before the offering period for which such change is to be effective.

A participant may not assign, transfer, pledge or otherwise dispose of (other than by will or the laws of descent and distribution) payroll deductions credited to a participant s account or any rights to exercise an option or to receive shares of our common stock under the ESPP, and during a participant s lifetime, options in the ESPP shall be exercisable only by such participant. Any such attempt at assignment, transfer, pledge or other disposition will not be given effect.

Adjustments upon Changes in Recapitalization, Dissolution, Liquidation, Merger or Asset Sale. In the event of any increase or decrease in the number of issued shares of our common stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock, or any other increase or decrease in the number of shares of common stock effected without receipt of consideration by us, we will proportionately adjust the aggregate number of shares of our common stock offered under the ESPP, the number and price of shares which any participant has elected to purchase pursuant under the ESPP and the maximum number of shares which a participant may elect to purchase in any single offering period.

If there is a proposal to dissolve or liquidate us, then the ESPP will terminate immediately prior to the consummation of such proposed dissolution or liquidation, and any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our dissolution or liquidation. We will notify each participant of such change in writing at least ten business days prior to the new exercise date. If we undergo a merger with or into another corporation or sale of all or substantially all of our assets, each outstanding option will be assumed or an equivalent option substituted by the successor corporation or the parent or subsidiary of the successor corporation. If the successor corporation refuses to assume the outstanding options or substitute equivalent options, then any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our proposed sale or merger. We will notify each participant of such change in writing at least ten business days prior to the new exercise date.

Amendment and Termination. Our board of directors may amend, suspend or terminate the ESPP at any time. Unless it is sooner terminated by our board of directors, the ESPP will terminate upon the earlier of (i) the

Table of Contents

Index to Financial Statements

tenth anniversary of the date of the ESPP s initial approval by our stockholders or (ii) the date on which all shares available for issuance under the ESPP shall have been sold pursuant to options exercised under the ESPP. However, the board of directors may not amend the ESPP without obtaining stockholder approval within 12 months before or after such amendment to the extent required by applicable laws.

We intend to file with the SEC a registration statement on Form S-8 covering our shares issuable under the ESPP.

Amended and Restated 2003 Stock Plan, as Amended

Our board of directors initially adopted the 2003 Plan on December 17, 2002. Our board of directors then approved an amendment and restatement of the 2003 Plan on April 4, 2013 and approved an increase of 227,272 shares to the 2003 Plans share reserve on January 30, 2014.

Following the effectiveness of the registration statement to which this prospectus relates, we will not make any further grants under the 2003 Plan. As discussed above, upon the completion of this offering, the shares of our common stock that were available for issuance upon the effectiveness of the registration statement to which this prospectus relates under the 2003 Plan became available for issuance under the 2014 Plan. However, the 2003 Plan will continue to govern the terms and conditions of the outstanding awards granted under the 2003 Plan, which constitute all of our outstanding stock options and restricted stock awards outstanding as of the date of this prospectus, excluding the options to purchase 187,909 shares of common stock that were granted coincident with this offering under the 2014 Plan.

Types of Awards. The 2003 Plan provides for the grant of non-qualified options and stock purchase rights to employees, non-employee members of the board of directors, consultants and other persons having a unique relationship with us or our subsidiaries. The 2003 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Code, to employees of such company or a parent corporation or subsidiary corporation thereof (as such terms are defined in Section 424(e) and (f) of the Code).

Share Reserve. As of January 31, 2014, we had reserved an aggregate of 2,063,087 shares of our common stock for issuance under the 2003 Plan. As of January 31, 2014, options to purchase a total of 1,638,544 shares of our common stock were issued and outstanding, a total of 303,158 shares of common stock had been issued upon the exercise of options or pursuant to other awards granted under the 2003 Plan, of which 170 shares had been repurchased and returned to the 2003 Plan, and 121,555 shares remained available for future grants. Such remaining share balance became available for issuance under the 2014 Plan upon the effectiveness of the registration statement to which this prospectus relates.

Administration. Our board of directors or a committee appointed by our board of directors administers the 2003 Plan. The administrator has the authority to select the employees to whom options and/or stock purchase rights will be granted under the 2003 Plan, the number of shares to be subject to those awards under the 2003 Plan, and the terms and conditions of the awards granted. In addition, the administrator has the authority to construe and interpret the 2003 Plan and to adopt rules for the administration, interpretation and application of the 2003 Plan that are consistent with the terms of the 2003 Plan.

Payment. The exercise price of options or purchase price of stock purchase rights granted under the 2003 Plan may be paid in such form as determined by the administrator, including, without limitation, cash, check, promissory notice, other shares, provided shares acquired directly from the Company have been owned by the holder for more than six months on the date of surrender and have a fair market value on the date of surrender equal to the aggregate exercise price or purchase price of the shares as to which such award relates, consideration received by the Company under a cashless exercise program implemented by the Company, or any combination of the foregoing methods of payment.

Transfer. The 2003 Plan does not allow for the transfer of awards other than by will or the laws of descent and distribution. If the administrator makes an award transferable, such option or stock purchase right may only be transferred by will, by the laws of descent and distribution, or to family members (within the meaning of

Table of Contents

Index to Financial Statements

Rule 701 of the Securities Act) through gifts or domestic relations orders, as permitted by Rule 701 of the Securities Act.

Certain Events. In the event of a dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off combination, repurchase, or exchange of shares or other securities of the Company, or other change in the corporate structure of the Company affecting shares occurs, the administrator may make appropriate adjustments to the number of shares available reserved for issuance under the 2003 Plan, the number of shares covered by each outstanding option or stock purchase agreement, and/or the exercise price or purchase price under each outstanding option or stock purchase agreement. In the event of a proposed dissolution or liquidation of the Company, the administrator will notify each holder as soon as practicable prior to the effective date of such proposed transaction, and then all such awards will terminate immediately prior to the consummation of such proposed action. In the event that we are a party to a merger or change in control, outstanding options may be assumed or substituted by the surviving corporation or its parent. In the event the successor corporation refuses to assume or substitute for the option or stock purchase right, then the vesting of such awards will be fully accelerated and the administrator will notify the holder in writing or electronically that such awards will be fully exercisable and vested for a period of 15 days from the date of such notice, and such awards will terminate upon expiration of such period.

Amendment; Termination. Our board of directors may amend or terminate the 2003 Plan or any portion thereof at any time; an amendment of the 2003 Plan shall be subject to the approval of our stockholders only to the extent required by applicable laws. Unless terminated sooner by our board of directors or extended with stockholder approval, the 2003 Plan will terminate ten years from the later of (i) the effective date of the Amended and Restated 2003 Plan and (ii) the earlier of the most recent board or shareholder approval of an increase in the number of shares reserved for issuance under the Plan. No awards may be granted under our 2003 Plan after it is terminated.

We intend to file with the SEC a registration statement on Form S-8 covering the shares of our common stock issuable pursuant to outstanding awards under the 2003 Plan.

Table of Contents

Index to Financial Statements

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2011 to which we have been a party, in which the amount involved exceeds $120,000, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

Funding Agreement with The Wellcome Trust Limited

In March 2010, we entered into a funding agreement with The Wellcome Trust Limited as trustee of the Wellcome Trust, which provided an unsecured convertible loan up to a maximum amount of $5.6 million to progress our plazomicin program. The Wellcome Trust Limited as trustee of the Wellcome Trust became a holder of more than 5% of our capital stock in April 2010 following conversion of an earlier loan by it to us into 774,749 shares of our Series C convertible preferred stock.

In March 2013, The Wellcome Trust Limited as trustee of the Wellcome Trust converted the full amount of the loan outstanding under the March 2010 funding agreement into 583,162 shares of our Series D convertible preferred stock.

Sales of Convertible Promissory Notes

In November 2012, we sold convertible promissory notes with an aggregate principal amount of $2.7 million in a bridge financing to existing stockholders, which we refer to as the 2012 Bridge Notes. The 2012 Bridge Notes earned simple interest of 6% per annum and were convertible into shares of our convertible preferred stock. The table below sets forth the principal amount of convertible promissory sold to our 5% stockholders and their affiliates in November 2012.

Name	Principal Amount
5AM Co-Investors LLC	$ 23,241.13
5AM Ventures LLC	$ 164,061.89
Alta Partners VIII, L.P.(1)	$ 235,890.06
ARCH Venture Fund VI, L.P.	$ 447,527.97
Domain Partners VII, L.P.	$ 626,832.05
DP VII Associates, L.P.	$ 10,691.42
Frazier Healthcare VI, L.P.(1)	$ 336,985.79
Venrock Associates IV, L.P.	$ 364,287.67
Venrock Entrepreneurs Fund IV, L.P.	$ 8,950.56
Venrock Partners, L.P.	$ 74,289.62
Versant Affiliates Fund II-A, L.P.	$ 7,277.46
Versant Side Fund II, L.P.	$ 3,426.86
Versant Venture Capital II, L.P.	$ 383,502.95

(1) Alta Partners VIII, L.P. and Frazier Healthcare VI, L.P. were holders of more than 5% of our capital stock at the time of the sale of the 2012 Bridge Notes, but were no longer holders of more than 5% of our capital stock at January 31, 2014.

Table of Contents

Index to Financial Statements

Sales of Series D Preferred Stock

In March, May and November 2013, we sold an aggregate of 2,092,572 shares of our Series D convertible preferred stock at a price of $11.99 per share for aggregate gross proceeds of $25.1 million, inclusive of amounts of principal and accrued interest from the 2012 Bridge Notes that were converted. The table below sets forth the number of shares of Series D convertible preferred stock sold to our 5% stockholders and their affiliates:

Name	Number of Shares of Series D Convertible Preferred Stock Purchased	Aggregate Purchase Price
5AM Co-Investors LLC	16,153	$ 193,676.65
5AM Ventures LLC	114,026	$ 1,367,182.64
Alta Partners VIII, L.P.(1)	103,400	$ 1,239,768.18
ARCH Venture Fund VI, L.P.	311,042	$ 3,729,400.12
Domain Partners VII, L.P.	435,663	$ 5,223,601.55
DP VII Associates, L.P.	7,430	$ 89,095.51
Frazier Healthcare VI, L.P.(1)	28,567	$ 342,524.87
Omega Fund IV, L.P.	194,322	$ 2,329,920.78
Venrock Associates IV, L.P.	311,692	$ 3,737,197.98
Venrock Entrepreneurs Fund IV, L.P.	7,658	$ 91,822.69
Venrock Partners, L.P.	63,563	$ 762,130.18
Versant Affiliates Fund II-A, L.P.	5,058	$ 60,648.69
Versant Side Fund II, L.P.	2,382	$ 28,563.45
Versant Venture Capital II, L.P.	266,543	$ 3,195,850.57
The Wellcome Trust Limited as trustee of the Wellcome Trust	217,567	$ 2,608,621.79

(1) Alta Partners VIII, L.P. and Frazier Healthcare VI, L.P. were holders of more than 5% of our capital stock at the time of the sale of the Series D convertible preferred stock to them at the initial closing, but were no longer holders of more than 5% of our capital stock at January 31, 2014.

Additionally, as noted above under Funding Agreement with The Wellcome Trust Limited, following the initial closing of the Series D convertible preferred stock financing, The Wellcome Trust Limited as trustee of the Wellcome Trust also converted the $5.6 million principal amount of the loan outstanding under our March 2010 funding agreement into 583,162 shares of our Series D convertible preferred stock at a conversion price equal to $9.59 per share, a 20% discount to the per share price in the Series D convertible preferred stock financing, in accordance with the terms of the funding agreement.

Investor Rights Agreement

We and the holders of our convertible preferred stock, as well as certain warrant holders, have entered into a third amended and restated investor rights agreement, pursuant to which these stockholders and warrant holders will have, among other things, registration rights under the Securities Act with respect to their shares of common stock following this offering. Prior to the completion of this offering, all outstanding shares of our convertible preferred stock will be converted into common stock. See Description of Capital Stock Registration Rights for more information about the investor rights agreement.

Voting Agreement

We have entered into an amended and restated voting agreement with certain holders of our common stock and holders of our convertible preferred stock. Upon the closing of this offering, the voting agreement will terminate. For a description of the amended and restated voting agreement, see the section titled Management Voting Arrangements.

147

Table of Contents

Index to Financial Statements

Right of First Refusal and Co-Sale Agreement

We have entered into an amended and restated right of first refusal and co-sale agreement with certain holders of our common stock and holders of our convertible preferred stock. This agreement provides for rights of first refusal and co-sale relating to the shares of our common stock held by certain key holders of our common stock and holders of our convertible preferred stock. Upon the closing of this offering, the amended and restated right of first refusal and co-sale agreement will terminate.

Director and Executive Officer Compensation

Please see Executive and Director Compensation for information regarding compensation of directors and executive officers.

Employment Agreements

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see Executive and Director Compensation Narrative to Summary Compensation Table and Outstanding Equity Awards at 2013 Fiscal Year End.

Indemnification Agreements and Directors and Officers Liability Insurance

We have entered into indemnification agreements with each of our directors and intend to enter into indemnification agreements with each of our executive officers. These agreements, among other things, require or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person s services as a director or executive officer.

Policies and Procedures for Related Party Transactions

In connection with our transition to becoming a public company, our board of directors has adopted a written related person transaction policy to set forth the policies and procedures for the review and approval or ratification of related person transactions, to be effective upon the completion of this offering. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had, has or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person.

As provided by our audit committee charter to be effective upon consummation of this offering, our audit committee will be responsible for reviewing and approving in advance the related party transactions covered by the company s related transaction policies and procedures.

Table of Contents

Index to Financial Statements

PRINCIPAL STOCKHOLDERS

The following table sets forth information relating to the beneficial ownership of our common stock as of January 31, 2014, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our current directors;
- each of our named executive officers; and
- all current directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of January 31, 2014 through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned before the offering is computed on the basis of 10,780,647 shares of our common stock outstanding as of January 31, 2014, which reflects the assumed conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 10,386,894 shares of common stock. In addition, the percentage of shares beneficially owned after the offering gives effect to the issuance of 6,000,000 shares in the offering. Shares of our common stock that a person has the right to acquire within 60 days of January 31, 2014 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Achaogen, Inc., at 7000 Shoreline Court, Suite 371, South San Francisco, California 94080.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned Before Offering	Percentage of Shares Beneficially Owned After Offering
5% and Greater Stockholders			
Entities Affiliated with Domain Partners(1)	2,020,939	18.75%	12.04%
Entities Affiliated with Venrock(2)	1,746,461	16.20%	10.41%
The Wellcome Trust Limited as trustee of the Wellcome Trust(3)	1,575,478	14.61%	9.39%
ARCH Venture Fund VI, L.P.(4)	1,418,657	13.16%	8.45%
Entities Affiliated with Versant Venture Capital(5)	1,281,152	11.88%	7.63%
Omega Fund IV, L.P.(6)	886,299	8.22%	5.28%
Entities Affiliated with 5AM Ventures(7)	601,281	5.58%	3.58%
Named Executive Officers and Directors			
Kenneth J. Hillan, M.B., Ch.B.(8)	569,270	5.02%	3.28%
Becki Filice(9)	122,260	1.12%	*
Dennis Hom(10)	95,081	*	*
Bryan E. Roberts, Ph.D.(2)	1,746,461	16.20%	10.41%
John C. Doyle(11)	67,801	*	*
Scott M. Rocklage, Ph.D.			

Camille D. Samuels			
John W. Smither(12)	1,010	*	*
Christopher T. Walsh, Ph.D.(13)	22,868	*	*
All current directors and executive officers as a group (11 persons)(14)	2,698,741	23.00%	15.22%

Table of Contents

Index to Financial Statements

* Indicates beneficial ownership of less than 1% of the total outstanding common stock.

(1) Includes (i) 1,987,049 shares of common stock held by Domain Partners VII, L.P. and (ii) 33,890 shares of common stock held by DP VII Associates, L.P. James C. Blair, Brian H. Dovey, Jesse I. Treu, Kathleen K. Schoemaker, Brian K. Halak and Nicole Vitullo, the managing members of One Palmer Square Associates VII, L.L.C., the general partner of Domain Partners VII, L.P. and DP VII Associates, L.P., share voting and investment power with respect to these shares. and therefore each of the foregoing managing members may be deemed to have voting and investment power with respect to such shares. Each of the foregoing managing members disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein, if any. The address of each of the persons and entities affiliated with Domain Partners is One Palmer Square, Suite 515, Princeton, New Jersey 08542.

(2) Includes (i) 289,912 shares of common stock held by Venrock Partners, L.P., (ii) 1,421,623 shares of common stock held by Venrock Associates IV, L.P. and (iii) 34,926 shares of common stock held by Venrock Entrepreneurs Fund IV, L.P. Venrock Management IV, LLC, Venrock Partners Management, LLC and VEF Management IV, LLC, collectively referred to in this note as the Venrock GP Entities, are the sole general partners of Venrock Associates IV, L.P., Venrock Partners, L.P. and Venrock Entrepreneurs Fund IV, L.P., respectively, collectively referred to in this note as the Venrock IV Funds, and have voting and investment power over the shares held by the Venrock IV Funds. Bryan E. Roberts is a Member of each of the Venrock GP Entities and may therefore be deemed to have voting and investment power with respect to the shares held by the Venrock IV Funds, but each of Dr. Roberts and the Venrock GP Entities disclaims beneficial ownership of the shares held by the Venrock IV Funds, except to the extent of their respective pecuniary interests therein. The address of each of the persons and entities affiliated with Venrock is 3340 Hillview Avenue, Palo Alto, CA 94304.

(3) Responsibility for the activities of The Wellcome Trust lies with the Board of Governors of The Wellcome Trust Limited, which is comprised of William Castell, Alan Brown, Damon Buffini, Kay Davies, Michael Ferguson, Richard Hynes, Anne Johnson, Eliza Manningham-Buller, Peter Rigby, and Peter Smith. The Board of Governors share all voting and investment power with respect to the shares held by The Wellcome Trust Limited as trustee of the Wellcome Trust. The address of each of the persons and entities affiliated with The Wellcome Trust Limited as trustee of the Wellcome Trust is 215 Euston Road, London NW1 2BE, United Kingdom.

(4) Shares held of record by ARCH Venture Fund VI, L.P., referred to herein as ARCH VI. ARCH Venture Partners VI, L.P., referred to herein as ARCH GPLP, as the sole general partner of ARCH VI, may be deemed to beneficially own certain of the shares held of record by ARCH VI. ARCH GPLP disclaims beneficial ownership of all shares held of record by ARCH VI in which ARCH GPLP does not have an actual pecuniary interest. ARCH Venture Partners VI, LLC, referred to herein as ARCH GPLLC, as the sole general partner of ARCH GPLP, may be deemed to beneficially own certain of the shares held of record by ARCH VI. ARCH GPLLC disclaims beneficial ownership of all shares held of record by ARCH VI in which it does not have an actual pecuniary interest. Keith Crandell, Clinton Bybee and Robert Nelsen are the managing directors of ARCH GPLLC, and may be deemed to beneficially own certain of the shares held of record by ARCH VI. The managing directors disclaim beneficial ownership of all shares held of record by ARCH VI in which they do not have an actual pecuniary interest. The address of each of the persons and entities affiliated with ARCH Venture Fund VI, L.P. is 8725 West Higgins Road, Suite 290, Chicago, IL 60631.

(5) Includes (i) 1,246,895 shares of common stock held by Versant Venture Capital II, L.P., referred to herein as VVC II, (ii) 23,118 shares of common stock held by Versant Affiliates Fund II-A, L.P, referred to herein as VAF II-A, and (iii) 11,139 shares of common stock held by Versant Side Fund II, L.P., referred to herein as VSF II. Versant Ventures II, LLC, referred to herein as VV II, serves as the sole general partner of VAF II-A, VSF II and VVC II and owns no shares directly. Brian G. Atwood, Ross A. Jaffe, M.D., Samuel D. Colella, Donald B. Milder, Rebecca B. Robertson, Bradley J. Bolzon, Ph.D., William J. Link, Ph.D., Charles M. Warden, and Barbara N. Lubash, as managing directors of VV II, share voting and investment authority over the shares held by VAF II-A, VSF II and VVC II; however, they disclaim beneficial ownership of the shares held by VAF II-A, VSF II and VVC II except to the extent of their pecuniary interests therein. The address of each of the persons and entities affiliated with Versant Venture Capital is c/o Versant Ventures, 3000 Sand Hill Road Building 4, Suite 210 Menlo Park, California 94025.

(6) Shares held of record by Omega Fund IV, L.P., referred to herein as Omega IV. Omega Fund IV GP, L.P. is the general partner of Omega IV. Omega Fund IV GP Manager, Ltd., referred to herein as Omega IV GP Ltd, is the general partner of Omega Fund IV GP, L.P. Otello Stampacchia, Renee Aguiar-Lucander, Richard Lim, and Anne-Mari Paster are all the shareholders and all the directors of Omega IV GP Ltd. Together they have shared voting and investment power over the shares held by Omega IV. The address of Omega IV and the above named individuals is c/o Omega Fund Management Limited, 1 Royal Plaza, Royal Avenue, St. Peter Port, Guernsey, GY1 2HL. The address of Omega IV GP LP and Omega IV GP Ltd is c/o Omega Fund Management (US) Inc., 545 Boylston St., Suite 802, Boston, MA 02116.

(7) Includes (i) 526,443 shares of common stock held by 5AM Ventures LLC and (ii) 74,838 shares of common stock held by 5AM Co-Investors LLC. John D. Diekman, Ph.D. and Andrew J. Schwab are the managing members of 5AM Ventures LLC and 5AM Co-Investors LLC and may be deemed to have voting and investment power over the shares held by 5AM Ventures LLC and 5AM Co-Investors LLC. Dr. Diekman and Mr. Schwab disclaim beneficial ownership of such shares, except to the extent of their pecuniary interest therein, if any. The address of each of the persons and entities affiliated with 5AM Ventures is 2200 Sand Hill Road, Suite 110, Menlo Park, CA 94025.

(8) Consists of 569,270 shares that may be acquired pursuant to the exercise of stock options within 60 days of January 31, 2014 by Dr. Hillan.

(9) Consists of 122,260 shares that may be acquired pursuant to the exercise of stock options within 60 days of January 31, 2014 by Ms. Filice.

(10) Consists of 95,081 shares that may be acquired pursuant to the exercise of stock options within 60 days of January 31, 2014 by Mr. Hom.

(11) Consists of 67,801 shares that may be acquired pursuant to the exercise of stock options within 60 days of January 31, 2014 by Mr. Doyle.

(12) Consists of 1,010 shares that may be acquired pursuant to the exercise of stock options within 60 days of January 31, 2014 by Mr. Smither.

(13) Consists of 22,868 shares that may be acquired pursuant to the exercise of stock options within 60 days of January 31, 2014 by Dr. Walsh.

(14) Includes: (i) 1,746,461 shares held by entities affiliated with Dr. Roberts and (ii) 952,280 shares that may be acquired by our current executive officers and directors pursuant to the exercise of stock options within 60 days of January 31, 2014.

Table of Contents

Index to Financial Statements

DESCRIPTION OF CAPITAL STOCK

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective immediately prior to the closing of this offering, the amended and restated investor rights agreement to which we and certain of our stockholders are parties and of the General Corporation Law of the State of Delaware. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, and amended and restated investor rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the consummation of this offering, we will have authorized under our amended and restated certificate of incorporation 290,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share.

The following information gives effect to the 1-for-11 reverse stock split that occurred on March 10, 2014 and assumes the conversion of all outstanding shares of our convertible preferred stock into shares of common stock immediately prior to the consummation of this offering: As of January 31, 2014, there were 10,780,647 shares of our common stock outstanding held by 71 stockholders of record. As of January 31, 2014, there were outstanding options to purchase 1,638,544 shares of common stock and outstanding warrants to purchase 40,454 shares of common stock.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. In the election of directors, a plurality of the votes cast at a meeting of stockholders is sufficient to elect a director. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In all other matters, except as noted below under Amendment of our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws and Election and Removal of Directors and except where a higher threshold is required by law, a majority of the votes cast affirmatively or negatively (excluding abstentions and broker non-votes) will decide such matters.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Table of Contents

Index to Financial Statements

Other Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of our company or other corporate action. Upon consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Warrants

The following table sets forth information about outstanding warrants to purchase shares of our stock as of January 31, 2014. Immediately prior to the consummation of this offering, all warrants to purchase shares of our convertible preferred stock will convert into warrants to purchase shares of our common stock, and the following table reflects that conversion.

Class of Stock	Number of Shares	Exercise Price/Share	Expiration Date
Common stock	10,430	$ 13.42	March 15, 2015
Common stock	30,024	$ 11.99	November 1, 2021

Registration Rights

We are party to an amended and restated investor rights agreement, which provides certain of our preferred stockholders and warrantholders the right to demand that we file a registration statement for their shares of common stock or request that their shares of common stock be covered by a registration statement that we are otherwise filing, in each case, to the extent their shares of common stock were issued upon conversion of convertible preferred stock or upon the exercise of such warrants.

Pursuant to the amended and restated investor rights agreement, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, these holders are entitled to notice of such registration and are entitled to certain piggyback registration rights allowing the holder to include their common stock in such registration, subject to certain marketing and other limitations. Certain of our stockholders also have the right, beginning 180 days following the effective date of the registration statement to which this prospectus relates, to require us, on not more than two occasions, to file a registration statement under the Securities Act to register the resale of their shares of common stock with anticipated gross proceeds, before deduction of underwriting discounts and expenses related to issuance, in excess of $5.0 million. We may, in certain circumstances, defer such registrations, and any underwriters will have the right, subject to certain limitations, to limit the number of shares included in such registrations. Further, certain of our preferred stockholders and warrantholders may require us to register the resale of all or a portion of

Table of Contents

Index to Financial Statements

their shares of common stock on a registration statement on Form S-3 once we are eligible to use Form S-3, subject to certain conditions and limitations. In an underwritten offering, the underwriter has the right, subject to specified conditions, to limit the number of registrable securities such holders may include.

The holders of registration rights have waived their rights to include any of their shares in this offering.

Anti-Takeover Effects of Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our charter documents provide that a special meeting of stockholders may be called only by our board of directors, the chairman of our board of directors, our Chief Executive Officer or, in the absence of a Chief Executive Officer, our President.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Election and Removal of Directors

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see

Table of Contents

Index to Financial Statements

Management Board Composition. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors. Our amended and restated certificate of incorporation provides that directors may be removed only for cause with the vote of holders of 66 2/3% of the voting power of all the then-outstanding shares of our voting stock. Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed interested stockholders from engaging in a business combination with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation s voting stock. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Amendment of our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws

The amendment of any of the above provisions in our amended and restated certificate of incorporation, except for the provision making it possible for our board of directors to issue preferred stock, or the amendment of any provision in our amended and restated bylaws (other than by action of the board of directors), would require approval by holders of at least 66 2/3% of our then outstanding voting stock.

The provisions of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Delaware as Sole and Exclusive Forum

Our amended and restated certificate of incorporation provides that unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by, or otherwise wrongdoing by, any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or the bylaws, or (v) any action asserting a claim against us or any of our directors, officers or employees governed by the internal affairs doctrine. Although our amended and restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could rule that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

Table of Contents

Index to Financial Statements

The NASDAQ Global Market Listing

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol AKAO.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar s address is 6201 15th Avenue, Brooklyn, New York 11219.

Table of Contents

Index to Financial Statements

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock, including shares issued upon the exercise of outstanding options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. Although our common stock has been approved for listing on The NASDAQ Global Market, we cannot assure you that there will be an active public market for our common stock.

Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of January 31, 2014, upon the closing of this offering and assuming (1) the conversion of our outstanding convertible preferred stock, (2) no exercise of the underwriters option to purchase additional shares of common stock, and (3) no exercise of outstanding options or warrants, we will have outstanding an aggregate of approximately 16,780,647 shares of common stock. All of the 6,000,000 shares of common stock to be sold in this offering, and any shares sold upon exercise of the underwriters option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our affiliates as such term is defined in Rule 144 of the Securities Act. All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be restricted securities as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701 under the Securities Act, the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market, subject to (1) any waivers by the underwriters under the lock-up agreements and (2) the volume limitations applicable to directors, executive officers and other affiliates under Rule 144, are as follows:

Approximate Number of Shares	First Date Available for Sale into Public Market
10,780,647 shares	180 days after the date of this prospectus

In addition, of the 1,638,544 shares of our common stock that were subject to stock options outstanding as of January 31, 2014, options to purchase 675,182 shares of common stock were vested as of January 31, 2014 and, upon exercise, these shares will be eligible for sale subject to the lock-up agreements described below and Rule 144 and Rule 701 under the Securities Act.

Lock-Up Agreements

In connection with this offering, we, our officers, directors and holders of substantially all of our outstanding capital stock and other securities have agreed with the underwriters not to issue, sell, transfer or otherwise dispose of our common stock or any securities convertible into or exercisable or exchangeable for our common stock for a period of 180 days from the date of this prospectus without the prior written consent of Credit Suisse Securities (USA) LLC and Cowen and Company, LLC, subject to certain exceptions, as described more fully in Underwriting.

Credit Suisse Securities (USA) LLC and Cowen and Company, LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the

Table of Contents

Index to Financial Statements

underwriters and any of our shareholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period.

Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our affiliates for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the sales proposed to be sold for at least one year, including the holding period of any prior owner other than affiliates, then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable).

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our affiliates, as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of common shares then outstanding, which will equal approximately 167,806 shares of common stock immediately after this offering (calculated on the basis of the assumptions described above and assuming no exercise of the underwriter s option to purchase additional shares and no exercise of outstanding options or warrants); or
- the average weekly trading volume of our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up

Table of Contents

Index to Financial Statements

agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701 persons who are not our affiliates, as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our affiliates may resell those shares without compliance with Rule 144 s minimum holding period requirements (subject to the terms of the lock-up agreement referred to above, if applicable).

Registration Rights

Upon the closing of this offering, the holders of 10,374,133 shares of our common stock, warrants to purchase our capital stock and the 40,454 shares of common stock issuable upon the exercise of those warrants will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up arrangement described above. 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, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See Description of Capital Stock Registration Rights.

Equity Incentive Plans

We intend to file with the SEC a registration statement under the Securities Act covering the shares of common stock that we may issue upon exercise of outstanding options under our Amended and Restated 2003 Stock Plan, the shares of common stock that we may issue pursuant to future awards under our 2014 Equity Incentive Award Plan, and the shares of common stock that may be purchased pursuant to our Employee Stock Purchase Plan. Such registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

Table of Contents

Index to Financial Statements

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended, referred to herein as the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, referred to herein as the IRS, in each case in effect as of the date of this prospectus. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder s particular circumstances, including the impact of the tax on net investment income imposed by Section 1411 of the Code. In addition, it does not address consequences relevant to Non-U.S. Holders subject to particular rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- controlled foreign corporations, passive foreign investment companies, and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and

tax-qualified retirement plans.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND

Table of Contents

Index to Financial Statements

DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a Non-U.S. Holder is any beneficial owner of our common stock that is neither a U.S. person nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled Dividend Policy, we do not anticipate paying any cash dividends in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under Sale or Other Taxable Disposition.

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the applicable withholding agent with the required certification, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

160

Table of Contents

Index to Financial Statements

Sale or Other Taxable Disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 or more days during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, referred to herein as a USRPI, by reason of our status as a U.S. real property holding corporation, referred to herein as a USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is regularly traded, as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually or constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder s holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Table of Contents

Index to Financial Statements

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends paid on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign financial institution or a non-financial foreign entity (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any substantial United States owners (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain specified United States persons or United States-owned foreign entities (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and IRS guidance, withholding under FATCA generally will apply to payments of dividends on our common stock made on or after July 1, 2014, and to payments of gross proceeds from the sale or other disposition of such stock on or after January 1, 2017.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

Table of Contents

Index to Financial Statements

UNDERWRITING

Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, we have agreed to sell to the underwriters named below, for whom Credit Suisse Securities (USA) LLC and Cowen and Company, LLC are acting as representatives, the following respective numbers of shares of common stock:

Underwriter	Number of Shares
Credit Suisse Securities (USA) LLC	2,700,000
Cowen and Company, LLC	1,800,000
William Blair & Company, L.L.C.	900,000
Needham & Company, LLC	600,000
Total	6,000,000

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock in the offering if any are purchased, other than those shares covered by the over-allotment option described below. The underwriting agreement also provides that if an underwriter defaults the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated.

We have granted to the underwriters a 30-day option to purchase on a pro rata basis up to 900,000 additional shares at the initial public offering price less the underwriting discounts and commissions. The option may be exercised only to cover any over-allotments of common stock.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel including the validity of the shares, and subject to other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer s certificates and legal opinions. The offering of the shares by the underwriters is also subject to the underwriters right to reject any order in whole or in part.

The underwriters propose to offer the shares of common stock initially at the public offering price on the cover page of this prospectus and to selling group members at that price less a selling concession of up to $0.504 per share. After the initial public offering the representatives may change the public offering price and selling concession to broker/dealers.

The following table summarizes the compensation we will pay:

	Per Share		Total	
	Without Over-allotment	With Over-allotment	Without Over-allotment	With Over-allotment
Underwriting discounts and commissions paid by us	$0.84	$0.84	$5,040,000	$5,796,000

We estimate that our out of pocket expenses for this offering (not including any underwriting discounts and commissions) will be approximately $3.4 million.

We have agreed to reimburse the underwriters for expenses of up to $45,000 related to clearance of this offering with the Financial Industry Regulatory Authority, Inc., or FINRA.

The underwriters have informed us that they do not expect sales to accounts over which the underwriters have discretionary authority to exceed 5% of the shares of common stock being offered.

We have agreed that we will not offer, sell, issue, contract to sell, pledge or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act

Table of Contents

Index to Financial Statements

relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, without the prior written consent of the representatives for a period of 180 days after the date of this prospectus. The restrictions described in this paragraph do not apply to (a) grants of employee stock options or other equity-based awards pursuant to the terms of our equity inventive plans, (b) issuances of shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock pursuant to the exercise of such options or other equity-based awards, (c) issuances of shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or option (d) issuances of shares of our common stock or securities convertible into or exercisable for any shares of our common stock in connection with a debt or credit financing facility or equipment leasing arrangement; provided, that the aggregate number of shares of our common stock or securities convertible into or exercisable for any shares of our common stock (on as-converted or as-exercised basis, as the case may be) that we may sell or issue or agree to sell or issue shall not exceed 2.5% of the total number of shares of our securities issued and outstanding immediately following the completion of this offering, (e) issuances of or entry into an agreement to sell or issue shares of our common stock or securities convertible into or exercisable for any shares of our common stock in connection with any (1) mergers, (2) acquisition of securities, businesses, property or other assets, (3) joint ventures or (4) strategic alliances; provided, that the aggregate number of shares of securities (on as-converted or as-exercised basis, as the case may be) that we may sell or issue or agree to sell or issue shall not exceed 10% of the total number of shares of our securities issued and outstanding immediately following the completion of this offering, or (f) the issuance of shares of our common stock in this offering, provided in the case of clauses (b), (c), (d) and (e), the recipients of such shares of our common stock or securities agree to be bound by a lockup letter in the form executed by our directors, officers and existing securityholders.

Our officers, directors and substantially all of our existing security holders have agreed that they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, enter into a transaction that would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any of these transactions are to be settled by delivery of our common stock or other securities, in cash or otherwise, or publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement, without, in each case, the prior written consent of the representatives for a period of 180 days after the date of this prospectus. The restrictions described in this paragraph do not apply to:

(a) transfers of our common stock or other securities as a bona fide gift or gifts or by testate succession or intestate distribution;

(b) any shares of our common stock acquired by the lock-up signatory in the open market;

(c) the exercise of stock options or other similar awards granted pursuant to our equity incentive plans, provided that such restrictions shall apply to any of the lock-up signatory s shares of common stock issued upon such exercise;

(d) any shares of our common stock or such other securities that are transferred to us for the primary purpose of satisfying any tax or other governmental withholding obligation, through cashless surrender or otherwise, with respect to any award of equity-based compensation granted pursuant to our equity incentive plans or in connection with tax or other obligations as a result of testate succession or intestate distribution;

(e) the exercise of warrants, whether for cash or through net exercise, to purchase our common stock or any security convertible into or exercisable or exchangeable for shares of our common stock, provided that such restrictions shall apply to any of the lock-up signatory s shares of common stock issued upon such exercise;

Table of Contents

Index to Financial Statements

(f) the establishment of any contract, instruction or plan, referred to herein as a Plan, that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act, provided that no sales of the lock-up signatory s shares of common stock shall be made pursuant to such a Plan prior to the expiration of the 180-day period referred to above, and provided that to the extent a public announcement or filing under the Exchange Act is required or voluntarily made by or on behalf of the lock-up signatory or us regarding the establishment of such Plan, such announcement or filing shall include a statement to the effect that no transfer of the lockup signatory s shares of common stock may be made under such Plan during the 180-day period referred to above;

(g) transfers not involving a disposition for value to a member or members of the lock-up signatory s family or to a trust, the direct or indirect beneficiaries of which are the lock-up signatory and/or a member or members of his or her family;

(h) distributions not involving a disposition for value of shares of our common stock or such other securities to members, partners or stockholders of the lock-up signatory or to any corporation, partnership or other person or entity that is a direct or indirect affiliate of the lock-up signatory;

(i) the transfer of the lock-up signatory s shares of our common stock or any security convertible into or exercisable or exchangeable for shares of our common stock that occurs because of operation of law; and

(j) the transfer of the lock-up signatory s shares of our common stock or any security convertible into or exercisable or exchangeable for shares of our common stock to us pursuant to any contractual arrangement in effect on the date of the lock-up agreement that provides for the repurchase of the lock-up signatory s shares of common stock or such other securities by us or in connection with the termination of the lock-up signatory s employment or other service relationship with us or the lock-up.

In the case of any transfer or distribution pursuant to clause (a), (g), (h) or (i), each done, distribute or transferee must execute a lock-up letter containing the foregoing restrictions. In the case of any transfer or distribution pursuant to clause (a) or (g) through (i), no filing by any party under the Exchange Act or other public announcement shall be required or voluntarily made (other than a filing on Form 5 after the expiration of the 180-day period referred to above).

We have agreed to indemnify the several underwriters against liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in that respect.

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol AKAO.

Prior to the offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representatives. In determining the initial public offering price, we and the representatives considered a number of factors including:

- the information set forth in this prospectus and otherwise available to the underwriters;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the recent market prices of, and demand for, publicly-traded common stock of generally comparable companies;

the general condition of the securities markets at the time of the offering; and

other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock, or that shares of our common stock will trade in the public market at or above the initial public offering price.

Table of Contents

Index to Financial Statements

In connection with the offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions, penalty bids and passive market making in accordance with Regulation M under the Exchange Act.

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, creating a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

In passive market making, market makers in the common stock who are underwriters or prospective underwriters may, subject to limitations, make bids for or purchases of our common stock until the time, if any, at which a stabilizing bid is made.

These stabilizing transactions, over-allotment transactions, syndicate covering transactions, penalty bids and passive market making may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The NASDAQ Global Market or otherwise and, if commenced, may be discontinued at any time.

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters, or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make Internet distributions on the same basis as other allocations.

Other Relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans,

166

Table of Contents

Index to Financial Statements

and may do so in the future. The underwriters are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities.

Selling Restrictions

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each such Member State referred to herein as a Relevant Member State, each underwriter represents and agrees that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, it has not made and will not make an offer of shares which are the subject of the offering contemplated by this prospectus to the public in that Relevant Member State other than:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

Each of the underwriters severally represents, warrants and agrees as follows:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity, within the meaning of Section 21 of the Financial Services and Markets Act 2000, or the FSMA, received by it in connection with the issue or sale of the shares in circumstances in which Section 21 of the FSMA does not apply to us; and

(b) it has complied with, and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

Table of Contents

Index to Financial Statements

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Latham & Watkins LLP, Menlo Park, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2012 and 2013, and for each of the two years in the period ended December 31, 2013, as set forth in their report. We have included our consolidated financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to Achaogen, Inc. and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street N.E., Room 1580, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at www.achaogen.com. You may access our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Index to Consolidated Financial Statements

Years Ended December 31, 2012 and 2013

Contents

Table of Contents

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Achaogen, Inc.

We have audited the accompanying consolidated balance sheets of Achaogen, Inc. as of December 31, 2012 and 2013, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders deficit and cash flows for each of the two years in the period ended December 31, 2013. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Achaogen, Inc. at December 31, 2012 and 2013, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company s recurring losses from operations and its need for additional funding raise substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Redwood City, California

February 12, 2014, except for the last paragraph of Note 2,

as to which the date is March 10, 2014

Table of Contents

Index to Financial Statements

Consolidated Balance Sheets

(in thousands except for share and per share amounts)

	December 31, 2012	December 31, 2013	Pro forma stockholders equity as of December 31, 2013 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 7,073	$ 10,738	
Contracts receivable	4,258	7,230	
Prepaids and other current assets	397	1,873	
Total current assets	11,728	19,841	
Property and equipment, net	1,344	743	
Restricted cash	127	127	
Deposit and other assets	67	47	
Total assets	$ 13,266	$ 20,758	
Liabilities, Convertible Preferred Stock, and Stockholders (Deficit) Equity			
Current liabilities:			
Accounts payable	$ 2,910	$ 2,923	
Accrued liabilities	1,567	3,004	
Related-party convertible notes payable	2,687		
Notes payable, current portion	4,536	4,989	
Other current liabilities	334	73	
Total current liabilities	12,034	10,989	
Deferred rent	69	125	
Derivative liability	1,398		
Related-party convertible loan payable	5,441		
Notes payable, noncurrent portion	6,311	1,698	
Other long-term liabilities	237	244	$
Total liabilities	25,490	13,056	
Commitments and contingencies (Note 7)			
Convertible preferred stock, $0.001 par value, 79,202,910 and 132,202,910 shares authorized at December 31, 2012 and 2013, respectively; 7,120,608 and 9,796,342 shares issued and outstanding at December 31, 2012 and 2013, respectively; liquidation value $100,727 and $132,809 at December 31, 2012 and 2013, respectively	100,354	132,278	
Stockholders (deficit) equity:			
Common stock, $0.001 par value, 105,000,000 and 163,000,000 shares authorized at December 31, 2012 and 2013, respectively; 373,840 and 392,844 shares issued and outstanding at December 31, 2012 and 2013, respectively			11
Additional paid-in capital	3,034	4,148	136,659
Accumulated deficit	(115,612)	(128,724)	(128,724)

Total stockholders (deficit) equity	(112,578)	(124,576)	7,946
Total liabilities, convertible preferred stock, and stockholders deficit	$ 13,266	$ 20,758	

See accompanying notes to consolidated financial statements.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands except for share and per share amounts)

	Year Ended December 31,	
	2012	2013
Contract revenue	$ 17,941	$ 18,512
Operating expenses:		
Research and development	26,581	23,484
General and administrative	7,349	6,992
Total operating expenses	33,930	30,476
Loss from operations	(15,989)	(11,964)
Interest expense and other, net	(2,427)	(1,341)
Interest income and other, net	51	193
Net loss and comprehensive loss	$ (18,365)	$ (13,112)
Basic and diluted net loss per common share	$ (52.77)	$ (33.83)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	347,993	387,547
Pro forma basic and diluted net loss per common share (unaudited) (Note 2)		$ (1.36)
Weighted-average common shares outstanding used to calculate pro forma basic and diluted net loss per common share (unaudited) (Note 2)		9,673,102

See accompanying notes to consolidated financial statements.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders Deficit

(in thousands except for share and per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at January 1, 2012	7,120,608	$ 100,354	323,906	$	$ 2,031	$ (97,247)	$ (95,216)
Issuance of common stock under stock plan			49,934		174		174
Stock-based compensation expense					829		829
Net loss and comprehensive loss						(18,365)	(18,365)
Balance at December 31, 2012	7,120,608	100,354	373,840		3,034	(115,612)	(112,578)
Sale of shares of Series D convertible preferred stock, net of issuance costs of $158	1,864,788	22,200					
Issuance of shares of Series D convertible preferred stock in exchange for convertible notes and interest payable to related parties	227,784	2,732					
Issuance of shares of Series D convertible preferred stock upon conversion of the related-party loan payable to The Wellcome Trust	583,162	6,992					
Issuance of common stock under stock plan			19,004		61		61
Stock-based compensation expense					1,053		1,053
Net loss and comprehensive loss						(13,112)	(13,112)
Balance at December 31, 2013	9,796,342	$ 132,278	392,844	$	$ 4,148	$ (128,724)	$ (124,576)

See accompanying notes to consolidated financial statements.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2012	**2013**
Cash flows from operating activities:		
Net loss	$ (18,365)	$ (13,112)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	565	506
Stock-based compensation expense	829	1,053
Loss on asset disposition		10
Non-cash interest expense relating to notes payable	524	472
Non-cash interest expense relating to related-party convertible loan payable	1,246	197
Non-cash restructuring charges		196
Change in operating assets and liabilities:		
Contracts receivable	631	(2,972)
Prepaids and other assets	98	(1,456)
Accounts payable and accrued liabilities	(1,911)	1,450
Other liabilities	(379)	(198)
Net cash used in operating activities	(16,762)	(13,854)
Cash flows from investing activities:		
Purchase of property and equipment	(568)	(110)
Change in restricted cash	35	
Net cash used in investing activities	(533)	(110)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs		22,200
Proceeds from issuance of related-party convertible notes payable	2,687	
Proceeds from the exercise of stock options, net of repurchases	174	61
Proceeds from issuance of related-party convertible loan payable	2,445	
Proceeds from issuance of notes payable	7,996	
Repayment of notes payable	(1,462)	(4,632)
Net cash provided by financing activities	11,840	17,629
Net (decrease) increase in cash and cash equivalents	(5,455)	3,665
Cash and cash equivalents, beginning of year	12,528	7,073
Cash and cash equivalents, end of year	$ 7,073	$ 10,738
Supplemental disclosures of cash flow information		
Interest paid	$ 699	$ 693
Supplemental disclosures of noncash investing and financing information		

Conversion of related-party convertible loan and notes payable to convertible preferred stock	$	$ 9,724

See accompanying notes to consolidated financial statements.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements

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 antibacterials to treat multi-drug resistant gram-negative infections. The Company is developing plazomicin, its lead product candidate, for the treatment of serious bacterial infections due to multi-drug resistant Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. The Company initiated a Phase 3 superiority trial of plazomicin in the first quarter of 2014.

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.

Basis of Presentation and Consolidation

The consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and include the consolidated accounts of the Company and its subsidiary. Intercompany accounts and transactions have been eliminated in consolidation. During 2012, the Company established a wholly owned foreign subsidiary in the United Kingdom. There have been no significant activities for this entity during the fiscal years ended December 31, 2012 and 2013.

The Company has incurred losses and negative cash flows from operations since its inception. As of December 31, 2013, the Company had cash and cash equivalents of approximately $10.7 million and an accumulated deficit of approximately $128.7 million. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company s research and development activities. Management plans to finance operations through equity or debt financing arrangements, government contracts, and/or third party collaboration funding; however, if the Company is unable to raise additional funding to meet its working capital needs, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations.

The Company will need to raise substantial additional funding in the near term in order to sustain operations. The negative cash flows and lack of financial resources of the Company raise substantial doubt as to the Company s ability to continue as a going concern.

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

2. Summary of Significant Accounting Policies

Use of Estimates

The accompanying financial statements have been prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

of contingent liabilities. On an ongoing basis, management evaluates its estimates, including those related to clinical trial accruals, fair value of liabilities, convertible preferred stock and related warrants, common stock and stock-based awards and income taxes. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Unaudited Pro Forma Stockholders Equity

Pro forma basic and diluted net loss per share has been computed to give effect to (i) the assumed conversion of the 9,796,342 shares of convertible preferred stock outstanding as of December 31, 2013 into 10,386,894 shares of common stock in connection with the Company s proposed initial public offering, or IPO, (ii) the conversion of all warrants exercisable for convertible preferred stock outstanding as of December 31, 2013 into warrants exercisable for shares of common stock, resulting in the reclassification of the related convertible preferred stock warrant liabilities, included in other long-term liabilities, to additional paid-in capital, which when added to the existing 392,844 shares of common stock outstanding as of December 31, 2013, results in a total of 10,779,738 shares of common stock. In addition, a common stock warrant for 909 shares was exercised in January 2014, increasing the number of common stock outstanding. The pro forma net loss per share attributable to common stockholders does not include the shares expected to be sold and related proceeds to be received from the IPO. For purposes of pro forma basic and diluted loss per share attributable to common stockholders, all shares of convertible preferred stock have been treated as though they had been converted to common stock in all periods in which such shares were outstanding.

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 certain related-party convertible notes payable approximate fair value due to their short-term maturities.

Cash and Cash Equivalents

Cash and cash equivalents are stated at fair value. Cash equivalents include only securities having an original maturity of three months or less at the time of purchase. The Company limits its credit risk associated with cash and cash equivalents by placing its investments with banks it believes are highly creditworthy and with highly rated money market funds. As of December 31, 2012 and 2013, cash and cash equivalents consisted of bank deposits, cash, and investments in money market funds.

Restricted Cash

At December 31, 2012 and 2013, 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.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

Customer Concentration

For the years ended December 31, 2012 and 2013, all of 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 and cash equivalents. Cash and cash equivalents are deposited in checking and money market accounts at one financial institution. Management believes that the financial institution is financially sound, and, accordingly, minimal credit risk exists with respect to this financial institution. The Company is exposed to credit risk in the event of default by the financial institution holding its cash and cash equivalents to the extent recorded in the balance sheets. Such deposits exceed federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Contracts Receivable

Contracts receivable represent amounts owed to the Company under certain government contracts. The Company had no amounts reserved for doubtful accounts as of December 31, 2012 and 2013, as the Company expects full collection of the receivable balances.

Property and Equipment, Net

Property and equipment consists of office equipment, laboratory equipment, and leasehold improvements and is stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized over their estimated useful lives or the remaining lease term, whichever is shorter. Maintenance and repair costs are charged as expense to the Company s consolidated statement of operations and comprehensive loss when incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment charge is determined based upon the excess of the carrying value of the asset over its estimated fair value, with estimated fair value determined based upon an estimate of discounted future cash flows or other appropriate measures of estimated fair value. For the year ended December 31, 2013, the Company recorded impairment charges of $194,000 related to the cessation of use of leasehold improvements and property and equipment in certain areas of leased property. See Note 14 for further information regarding the restructuring activities and the impairment.

Convertible Preferred Stock Warrant Liabilities

The Company accounts for its Series A and Series C convertible preferred stock warrant liabilities as freestanding warrants for shares that are puttable or redeemable. These warrants are classified as liabilities on the

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

consolidated balance sheets at their estimated fair value. At the end of each reporting period, changes in estimated fair value during the period are recorded as a component of interest expense and other, net. The Company will continue to adjust the liability for changes in estimated fair value until the earlier of the expiration of the warrants, exercise of the warrants, or conversion of the warrants, including upon the completion of an IPO, to common stock warrants that will no longer be subject to remeasurement.

Stock-Based Compensation

The Company uses the Black-Scholes option-pricing valuation model to estimate the grant-date fair value of stock option awards with time-based vesting terms. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions regarding a number of complex and subjective variables. The Company records stock-based compensation expense, net of the estimated impact of forfeited awards. As such, the Company recognizes stock-based compensation expense only for those stock-based awards that are expected to vest over their requisite service period, based on the vesting provisions of the individual underlying grants.

During 2012 and 2013, the Company also issued stock-based option awards with market-based conditions that vest upon achievement of certain market price thresholds of the Company s common stock. The estimated fair value for market-based stock option awards is determined using a lattice valuation model with a Monte-Carlo simulation. The model takes into consideration the historical volatility of the Company s stock and the risk-free interest rate at the date of grant. In addition, the model is used to estimate the derived service period for the awards. The derived service period is the estimated period of time that would be required to satisfy the market condition, assuming the market condition will be satisfied. Stock-based compensation expense is recognized over the implicit service period derived from the Monte-Carlo simulation model, as applicable, but is accelerated if the market condition is achieved earlier than estimated.

For non-employee stock-based awards, the measurement date on which the estimated fair value of the stock-based award is calculated is equal to the earlier of (i) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or (ii) the date at which the counterparty s performance is complete. The Company recognizes stock-based compensation expense for the estimated fair value of the vested portion of non-employee awards in its consolidated statements of operations and comprehensive loss.

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 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.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include certain payroll and personnel expenses; laboratory supplies; consulting costs; external contract research and development expenses; and allocated overhead, including rent, equipment depreciation and utilities, and relate to both Company-sponsored programs as well as costs incurred pursuant to collaboration agreements and government contracts. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

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

Leases

The Company enters into lease agreements for its laboratory and office facilities. These leases qualify as operating leases and are therefore classified as operating leases. Rent expense is recognized on a straight-line basis over the term of the lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Incentives granted under the Company s facilities leases, including allowances to fund leasehold improvements and rent holidays, are capitalized and are recognized as reductions to rental expense on a straight-line basis over the term of the lease.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company s lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The Company s policy is to recognize interest charges and penalties as interest expense and other, net.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merits, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement.

Net Loss and Unaudited Pro Forma Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. Because the Company has reported a net loss for the years ended December 31, 2012 and 2013, diluted net loss per common share is the same as basic net loss per common share for those periods.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

The following table sets forth the computation of the basic and diluted net loss per share during the years ended December 31, 2012 and 2013 (in thousands, except share and per share data):

	Years Ended December 31, 2012	2013
Net loss	$ (18,365)	$ (13,112)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	347,993	387,547
Basic and diluted net loss per common share	$ (52.77)	$ (33.83)

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares):

	December 31, 2012	2013
Convertible preferred stock	7,711,160	10,386,894
Warrants to purchase convertible preferred stock	40,454	40,454
Options to purchase common stock	1,340,433	1,405,550
Warrants to purchase common stock	909	909

The unaudited pro forma basic and diluted loss per share for the year ended December 31, 2012 and 2013 has been computed using the weighted-average number of shares of common stock outstanding after giving pro forma effect to the conversion of all shares of convertible preferred stock upon an IPO by treating all shares of convertible preferred stock as if they had been converted to common stock in all periods in which such shares were actually outstanding. The following table sets forth the computation of the Company s unaudited pro forma basic and diluted net loss per share during the year ended 2013 (in thousands, except for share and per share amounts):

	Year Ended December 31, 2013
Pro forma basic and diluted net loss per common share	
Numerator:	
Net loss	$ (13,112)
Denominator:	
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	387,547
Pro forma adjustments to reflect the assumed conversion of convertible preferred stock and warrants	9,285,555
Shares used to calculate pro forma basic and diluted net loss per common share	9,673,102
Pro forma basic and diluted net loss per common share	$ (1.36)

Reverse Stock Split

In February 2014, the Company s board of directors and stockholders approved an amended and restated certificate of incorporation to effect a reverse split of shares of our common stock and convertible preferred stock at a 1-for-11 ratio. The reverse split became effective on March 10, 2014. The par value and the authorized

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

shares of the common and convertible preferred stock were not adjusted as a result of the reverse split. All issued and outstanding common stock, convertible preferred stock, warrants for common stock, warrants for preferred stock, and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse split for all periods presented. Subject to the requisite stockholder approval, the reverse split is expected to be effected prior to the effectiveness of the registration statement to which this prospectus relates.

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, accrued liabilities, and certain related-party convertible notes 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.

The Company s financial instruments have consisted of Level 1 assets and Level 3 liabilities. Where quoted prices are available in an active market, securities are classified as Level 1 of the valuation hierarchy. Level 1 securities include highly liquid money market funds and fixed-income securities issued by the U.S. government or its agencies.

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.

The estimated fair values of the outstanding preferred stock warrant liabilities are measured using the Black-Scholes option-pricing model. Inputs used to determine estimated fair value include the estimated fair value of the underlying preferred stock at the measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends on convertible preferred stock and expected volatility of the price of the underlying convertible preferred stock.

The estimated fair value of the derivative liability associated with the convertible loan due to beneficial conversion features, or BCF, on certain of the Company s convertible loans is measured by multiplying (1) the intrinsic value of the 20% conversion discount on the effective date and (2) the number of shares converted.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at estimated fair value using Level 3 inputs. There were no transfers within the hierarchy during the years ended December 31, 2012 and 2013.

As of December 31, 2012 and 2013, financial assets 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):

As of December 31, 2013:

	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets				
Cash	$ 8,411	$	$	$ 8,411
Money market funds	2,327			2,327
Restricted cash	127			127
	$ 10,865	$	$	$ 10,865
Reported as:				
Cash and cash equivalents	$ 10,738			
Restricted cash	$ 127			
Liabilities				
Convertible preferred stock warrant liabilities	$	$	$ 244	$ 244

As of December 31, 2012:

	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets				
Cash	$ 5,246	$	$	$ 5,246
Money market funds	1,827			1,827
Restricted cash	127			127
	$ 7,200	$	$	$ 7,200
Reported as:				
Cash and cash equivalents	$ 7,073			
Restricted cash	$ 127			
Liabilities				

Convertible preferred stock warrant liabilities	$	$	$ 237	$ 237
Derivative liability in connection with convertible note payable			1,398	1,398
	$	$	$ 1,635	$ 1,635

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

The following table provides a summary of changes in the estimated fair value of the Company s liabilities measured at estimated fair value using significant Level 3 inputs for the years ended 2012 and 2013 (in thousands):

	Estimated Fair Value of Convertible Preferred Stock Warrant Liabilities	Estimated Fair Value of Derivative Liability
Balance at January 1, 2012	$ 126	$
Initial estimated fair value of convertible preferred stock warrant liabilities for newly issued warrants	163	
Change in estimated fair value of convertible preferred warrant liabilities included in interest income and other	(52)	
Initial estimated fair value of derivative liability		1,398
Balance at December 31, 2012	237	1,398
Change in estimated fair value of convertible preferred stock warrant liabilities included in interest income and other, net	7	
Extinguishment of derivative liability		(1,398)
Balance at December 31, 2013	$ 244	$

The changes in the estimated fair value of the warrant liabilities of $52,000 and $(7,000) are recorded as interest income and other, net for the years ended December 2012 and 2013.

4. Balance Sheet Components

Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31, 2012	2013
Office equipment	$ 1,126	$ 1,017
Laboratory equipment	2,823	2,739
Leasehold improvements	1,231	869
	5,180	4,625
Less: accumulated depreciation and amortization	(3,836)	(3,882)

Property and equipment, net	$ 1,344	$ 743

Depreciation and amortization expense for the years ended December 31, 2012 and 2013 was $565,000 and $506,000, respectively.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2012	2013
Accrued clinical and development expenses	$ 525	$ 1,429
Payroll and related expenses	737	760
Other	305	815
	$ 1,567	$ 3,004

5. License and Collaboration Agreements

Isis Pharmaceuticals

In January 2006, the Company entered into a license agreement with Isis Pharmaceuticals, Inc., or 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 preferred Series A convertible 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 will be 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 for 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 Company is also obligated to pay royalties equal to a low single-digit percentage of annual worldwide net sales of all licensed products, including plazomicin.

In December 2008, the Company met its first milestone under the license with Isis when it filed an Investigational New Drug application, or IND, for the first aminoglycoside product. The Company paid Isis $500,000 in cash and opted to pay the remaining amount of $500,000 in the form of 23,923 shares of Series B convertible preferred stock with a value of $20.90 per share. The $1,000,000 milestone payment was recorded as research and development expense.

In July 2010, the Company met its second milestone under the license with Isis when it initiated Phase 2 clinical trials for the first aminoglycoside product. The Company paid Isis $2,000,000 in cash and recorded the amount as research and development expense. There are no outstanding payments due as of December 31, 2012 and 2013.

University of Washington

In December 2006, the Company entered into a license agreement with the University of Washington, referred to herein as the UW Agreement. Under the UW Agreement, the University granted the Company rights to the licensed patents resulting from the University s research program on certain novel LpxC inhibitor antibacterial compounds and related technology. The Company paid an up-front fee, which was recorded as research and development expense in the Company s consolidated statements of operations and comprehensive loss. The Company is obligated to reimburse the University for all reasonable out-of-pocket costs related to

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

maintaining the licensed patents. For the years ended December 31, 2012 and 2013, the Company paid, and recorded as research and development expense in the Company s consolidated statements of operations and comprehensive loss, $26,000 and $1,000, respectively, in costs related to maintaining these patents. Since December 2009, and until the grant of regulatory approval for products covered by the UW Agreement, the Company has been and will continue to be obligated to pay a nominal annual license maintenance fee to the University. If the Company commercializes products covered by the licensed patents, the Company will be obligated to pay royalties equal to a low single-digit percentage of annual worldwide net sales of such products, subject to a specified minimum annual royalty following the regulatory approval to market a licensed product. In further consideration of this license, the Company may be obligated to make product development and regulatory milestone payments of up to $2,150,000 for the first product commercialized under the UW Agreement to achieve the specified milestone, and up to $1,075,000 for each of the second and third products to achieve the specified milestones.

In April 2012, the Company met its first milestone under the UW Agreement when it filed an IND for a product candidate from the Company s LpxC inhibitor program. During 2012, the Company paid $150,000 in cash and recorded the amount as research and development expense. At December 31, 2012 and 2013, the Company had $10,000 and zero, respectively, in outstanding payments due under the UW Agreement.

University of Montreal

In conjunction with its aminoglycoside program, the Company entered into a multi-year research collaboration with the University of Montreal effective April 2006. The research collaboration required a total three-year funding commitment of $450,000 by the Company through April 23, 2009. The collaboration agreement was renewed in April 2009 with an additional $450,000 funding commitment through April 2012. The agreement expired in April 2012. For the years ended December 31, 2012 and 2013, the Company paid, and recorded as research and development expense, $38,000 and zero, respectively.

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.

Defense Threat Reduction Agency

In June 2007, the Company was awarded a contract by the Defense Threat Reduction Agency, or DTRA, to develop novel antibacterials for the treatment of infections due to biodefense pathogens. The original contract provided the Company with up to $18,790,000 in funding over two years. The contract was subsequently modified to extend through the end of November 2012 and to provide for a total of $35.4 million of funding for drawdown. In November 2012, DTRA terminated the contract for convenience.

During the years ended December 31, 2012 and 2013, the Company recognized revenue of $1,542,000 and zero, respectively, under this agreement, of which $804,000 and zero were included in contracts receivable at December 31, 2012 and 2013, respectively.

National Institute for Allergy and Infectious Disease

In September 2008, the Company was awarded a contract by the National Institute for Allergy and Infectious Disease, or NIAID, to conduct research and development of extended-spectrum aminoglycoside

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

antibiotics for the treatment of serious gram-negative infections. As amended in September 2011, this contract provided the Company with up to $22,188,000 over a five-year term through August 2013. During the years ended December 31, 2012, and 2013, the Company recognized revenue of $2,561,000, and $168,000, respectively, under this agreement, of which $202,000 and $42,000 were included in contracts receivable at December 31, 2012 and 2013, respectively.

Biomedical Advanced Research and Development Authority

In August 2010, the Company was awarded a contract with the Biomedical Advanced Research and Development Authority, or 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. During the years ended December 31, 2012 and 2013, the Company recognized revenue of $11,609,000 and $18,073,000, respectively, under this agreement, of which $1,810,000 and $7,188,000 were included in contracts receivable at December 31, 2012, and 2013, respectively.

U.S. Army Medical Research Acquisition Authority

In May 2012, the Company was awarded a one-year, $2,499,000 contract by the U.S. Army Medical Research Acquisition Authority to support its Phase 1 clinical study of ACHN-975, a product candidate from its LpxC inhibitor program. The Company recognized revenue of $2,228,000 and $271,000 for the year ended December 31, 2012, and 2013, respectively, of which $1,442,000 and zero were included in contracts receivable at December 31, 2012 and 2013, respectively.

7. Commitments

Facility Lease Agreement

In December 2010, the Company entered into an amended and restated lease agreement for its facility in South San Francisco, consisting of approximately 35,000 square feet. As part of the amended and restated lease agreement, the landlord agreed to complete certain leasehold improvement work on the additional premises in the amount of $362,000. Such tenant allowance was recorded as a leasehold improvement and is being amortized over the term of the lease. In April 2013, the Company subleased 19,000 square feet to a subtenant. The sublease will expire in March 2014. In June 2013, the Company further amended its lease to extend the lease term through April 2017 for the remaining space of 16,234 square feet. This extension of the lease term does not include the space being subleased.

The Company has provided a letter of credit in the amount of $127,000 as a security deposit on the lease, which letter of credit is collateralized by a money market account. The Company records the collateralized deposit as restricted cash.

The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid. Aggregate rent expense, net of sublease income, was $957,000 and $673,000 for the years ended December 31, 2012 and 2013, respectively. The Company received $291,000 of sublease income

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

for the year ended December 31, 2013 and expects to receive sublease income of $97,000 through March 31, 2014, which is the end of both the lease and sublease term.

Future minimum payments under all noncancelable operating leases, excluding expected future sublease income, as of December 31, 2013, are as follows (in thousands):

2014	$ 439
2015	578
2016	595
2017	179
Total minimum lease payments	$ 1,791

Guarantees and Indemnifications

As permitted under Delaware law and in accordance with the Company s bylaws, the Company is required to indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its directors. The Company believes the fair value of the indemnification rights and agreements is minimal. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of December 31, 2012 and 2013.

8. Borrowings

Oxford Finance and SVB Loan Agreement

In November 2011, the Company entered into a loan and security agreement, referred to herein as the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or SVB, under which the Company could borrow up to $12,000,000 through June 30, 2012, with $8,000,000 being drawable by the Company at its option, and the remaining $4,000,000 being drawable upon the occurrence of an IND Event, as defined in the Loan Agreement.

The Company borrowed $4,000,000 in November 2011, and the remaining $8,000,000 in April 2012, upon the occurrence of an IND Event.

The interest rate, which was fixed at the closing of each tranche, equals the three-month LIBOR plus 7.75%. The interest rates for the tranches under the Loan Agreement are 8.18% and 8.22% per annum. Payments are monthly in arrears and interest only until September 1, 2012, followed by 30 equal monthly payments of principal and interest through the scheduled maturity date of February 1, 2015. In addition, a final payment equal to 8.25% of the aggregate amount drawn will be due on February 1, 2015, or upon termination of the Loan Agreement, which is being accreted as interest expense over the term of the loan using the effective-interest method.

In accordance with the terms of the Loan Agreement, the Company agreed to issue warrants to Oxford Finance LLC and SVB upon each drawdown to purchase preferred stock equal to 3% of the advanced amount using a share strike price equal to the lower of the price per share of the Company s Series C convertible preferred stock or the price per share in its next round convertible preferred stock financing. During 2011 and 2012, the Company issued warrants to Oxford Finance LLC and SVB to purchase 10,008 and 20,016 shares, respectively, of its Series C convertible preferred stock at an exercise price of $11.99 per share. The fair value of these warrants at the date of issuance was approximately $86,000 and $163,000 and was recorded as a debt discount and is being amortized as interest expense over the term of the loan using the effective-interest method.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

As of December 31, 2013, these warrants remained outstanding and exercisable. Immediately prior to the closing of the IPO, these warrants will automatically convert into warrants exercisable for shares of common stock, resulting in the reclassification of the related preferred stock warrant liabilities to additional paid-in capital.

The loans are secured by substantially all of the Company s assets, except for intellectual property. Under the Loan Agreement, the Company also agreed to certain restrictions regarding the pledging or encumbrance of its intellectual property. The Loan Agreement includes customary administrative covenants, but does not include any financial maintenance or operating related covenants. As of December 31, 2013, the Company was in compliance with all required covenants. In addition, Oxford Finance LLC and SVB were granted the rights, at their discretion, to participate in certain future equity financings, other than the Company s IPO, by investing up to $250,000 in the Company on the same terms, conditions, and pricing afforded to others participating in such subsequent offerings. Neither Oxford Finance LLC nor SVB exercised their right to participate in the Company s Series D financing. Future minimum debt obligation payments are as follows as of the dates indicated (in thousands):

	December 31, 2013
2014	$ 5,325
2015	1,878
Total minimum payments	7,203
Less amount representing interest payments	(1,297)
Present value of future obligation payments	5,906
Unamortized discount on notes payable	(39)
Accretion of the final payment	820
Less current portion	(4,989)
Notes payable, net of current portion	$ 1,698

The Company recorded interest expense related to the loan of $1,160,000 and $1,037,000 for the years ended December 31, 2012, and 2013, respectively. The annual effective interest rates of the notes payable, including the accretion of the final payments, are approximately 11.9% 13.1%.

Funding Agreement with The Wellcome Trust

In March 2010, the Company entered into a Funding Agreement, referred to herein as the 2010 Wellcome Funding Agreement, with The Wellcome Trust Limited, a company registered in England and Wales, as trustee for The Wellcome Trust, which is referred to herein as the Trust. Under the 2010 Wellcome Funding Agreement, the Trust provided an unsecured convertible loan of $5,594,000 to the Company to progress its aminoglycoside program. The funds were advanced to the Company in two tranches of (a) $3,148,000 upon the signing of the 2010 Wellcome Funding Agreement and (b) the remaining amount upon the satisfaction of a milestone defined under the 2010 Wellcome Funding Agreement.

The Trust, at its discretion, had the right to convert any outstanding balance on the loan into the Company s stock at a conversion price representing a 20% discount to the applicable share price: (a) after the first round of equity financing following the execution of the 2010 Wellcome Funding Agreement, using the share price from such round; (b) immediately prior to the completion of a sale of the Company, using the price per share paid in the sale; (c) in case of an IPO, prior to the admission to the trading of the Company s common stock on the

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

applicable exchange, using the share price in the IPO; and (d) in certain other circumstances, including the occurrence of an event of default, using the share price from the first round of equity financing following the execution of the 2010 Wellcome Funding Agreement, or if such has not yet occurred, using a share price determined by independent accountants appointed jointly by the parties. In addition, the Trust also had the right to demand repayment of the entire loan amount or part of the loan together with accrued interest, which accrued at the rate of 2% per annum above the three-month dollar LIBOR, upon the occurrence of certain circumstances related to a sale or IPO of the Company or in the event of default of the 2010 Wellcome Funding Agreement. In addition, the Trust was able to demand repayment of such amounts at any time after the third anniversary of the end of the drawdown period. However, the Trust could not require the Company to repay the loan and accrued interest if, as a result of such repayment, the Company would likely become insolvent.

The discount feature of the loan, and the control of conversion by the lender under this funding agreement created a beneficial conversion feature, or BCF, which is accounted for as derivative liability and recorded in long-term liabilities. The accounting for a BCF requires that the BCF be recognized by allocating the intrinsic value of the conversion option to additional paid-in capital, resulting in a discount on the convertible instrument. The fair value of the BCF is measured by multiplying (1) the intrinsic value of the 20% conversion discount on the effective date with (2) the number of shares converted.

In March 2013, the outstanding balance of the 2010 Wellcome Funding Agreement of $5,594,000, was converted into Series D convertible preferred stock at a conversion price that represented a 20% discount to the issue price. The debt discount was accreted over the life of the debt up to date of redemption, and the Company recorded interest expense related to the 2010 Wellcome Funding Agreement of $1,115,000 and $153,000 for the years ended December 31, 2012 and 2013, respectively. As of December 31, 2012 and 2013, $5,441,000 and zero, respectively, have been recorded as a net long-term liability.

Convertible Notes Purchase Agreement

In November 2012, the Company entered into a Note Purchase Agreement, referred to herein as the 2012 Bridge Loan Agreement, with a group of existing investors. Under the 2012 Bridge Loan Agreement, the investors severally agreed to purchase convertible promissory notes for a principal amount of up to $3,000,000 in aggregate. For value received, the Company agreed to pay to the investors the principal loan amount plus accrued interest calculated at a rate equal to 6% per annum, computed on the basis of the actual days elapsed and a year of 365 days, on the earlier of (a) May 31, 2013 or (b) when such amounts become automatically due and payable or are declared due and payable by the investors upon default. As of December 31, 2012 and 2013, $2,687,000 and zero, respectively, have been recorded as a current liability.

On March 6, 2013, the investors under the 2012 Bridge Loan Agreement converted the entire outstanding notes amount plus accrued interest into shares of the Company s Series D convertible preferred stock at a conversion price of $11.99 per share, which was the issuance price of Series D convertible preferred stock. The Company issued 227,784 shares of Series D convertible preferred stock to the investors upon conversion of outstanding loans and accrued interest in the aggregate of $2,732,000 under the 2012 Bridge Loan Agreement.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

9. Convertible Preferred Stock

The authorized, issued and outstanding shares of convertible preferred stock and liquidation preferences as of December 31, 2012 and 2013 were as follows:

As of December 31, 2013:

Series	Shares Authorized	Shares Outstanding	Liquidation Amount	Carrying Value
Series A	12,386,071	1,116,876	$ 17,200,000	$ 17,062,000
Series B	14,266,839	1,295,448	27,075,000	26,991,000
Series C	52,550,000	4,708,284	56,452,000	56,301,000
Series D	53,000,000	2,675,734	32,082,000	31,924,000
	132,202,910	9,796,342	$ 132,809,000	$ 132,278,000

As of December 31, 2012:

Series	Shares Authorized	Shares Outstanding	Liquidation Amount	Carrying Value
Series A	12,386,071	1,116,876	$ 17,200,000	$ 17,062,000
Series B	14,266,839	1,295,448	27,075,000	26,991,000
Series C	52,550,000	4,708,284	56,452,000	56,301,000
	79,202,910	7,120,608	$ 100,727,000	$ 100,354,000

The Company recorded Series A, B, C, and D convertible preferred stock at fair values on the dates of issuance, net of issuance costs. A redemption event will only occur upon the liquidation or winding up of the Company, a greater than 50% change of control, or a sale of substantially all of its assets. As the redemption event is outside of the Company s control, all shares of preferred stock have been presented outside of permanent equity in accordance with ASC 480-10-S99-3A, *Classification and Measurement of Redeemable Securities*.

In May 2013, the Company completed the first of two tranches of its Series D round of financing. The proceeds from the financing were received in two tranches. The majority of the first tranche was received in March 2013 and the Company issued 1,110,252 shares of Series D convertible preferred stock at $11.99 per share to the investors in exchange for cash proceeds of $10,581,000 and conversion of outstanding loans and accrued interest in the aggregate of $2,732,000 under the 2012 Agreement. The conversion price of $11.99 per share represented no discount to the issue price. The remaining amount of the first tranche was received in May 2013 from a new investor for additional cash proceeds of $1,778,000 for the issuance of 148,289 shares at a price of $11.99 per share. The second tranche was closed in November 2013. Under the terms of the stock purchase agreement, the Company issued 834,031 additional shares of Series D convertible preferred stock at $11.99 per share for gross cash proceeds of $10,000,000. The second tranche was not contingent upon specific Company milestones or achieving specific financial covenants.

The rights, privileges, and preferences of Series A, B, C, and D convertible preferred stock are listed below:

Conversion Rights

Each share of Series A, B, C, and D convertible preferred stock is convertible at the stockholders option at any time into common stock determined by dividing the original issue price of $15.40, $20.90, $11.99, and $11.99,

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

respectively, by the conversion price for such series. The conversion price is subject to adjustment for dilutive issuances, stock splits, reclassifications, and the like. As of December 31, 2013, the conversion prices of Series A, B, C, and D convertible preferred stock were $13.42, $15.73, $11.99, and $11.99 per share, respectively. As of December 31, 2012, the conversion prices of Series A, B, and C convertible preferred stock were $13.42, $15.73, and $11.99 per share, respectively. Conversion of all outstanding convertible preferred stock is automatic upon (a) the closing of a firmly underwritten public offering in which the aggregate valuation of the Company immediately prior to the offering is not less than $200,000,000 and the gross cash proceeds received by the Company before underwriting discounts, commissions, and fees are not less than $40,000,000 or (b) the written consent of the holders of at least a majority of the Company s outstanding preferred stock.

Dividends

Holders of the Series A, B, C, and D convertible preferred stock are each entitled to noncumulative dividends, if and when declared by the board of directors. Dividends to Series A, B, C, and D convertible preferred stockholders are to be paid in advance of any distributions to common stockholders. No dividends have been declared to date.

Voting

Each holder of shares of convertible preferred stock is entitled to voting rights equivalent to the number of shares of common stock into which the respective shares are convertible. Certain financing, acquisition, disposition, and recapitalization transactions require the vote of the majority of the shares of outstanding preferred stock, provided that at least 136,363 shares of convertible preferred stock are issued and outstanding.

Liquidation Preference

In the event of a liquidation or winding up of the Company, whether voluntary or involuntary, before payment is made to the holders of any other series of preferred stock or to the holders of common stock, holders of the Series A, B, C, and D convertible preferred stock are entitled to be paid a liquation preference of $15.40, $20.90, $11.99, and $11.99 per share, respectively, together with any declared but unpaid dividends. Any remaining assets would then be distributed among the holders of the common stock on a pro rata basis based on the number of shares of common stock held by them. If the holders of a series of convertible preferred stock would be entitled to greater proceeds if they had converted their shares of such series of preferred stock to common stock prior to such liquidation or winding up of the Company, such series will be deemed to have been so converted for the purpose of calculating the proceeds to be received the holders of such series of preferred stock. If assets are insufficient to make payment in full to all holders of Series A, B, C, and D convertible preferred stock, then the assets or consideration will be distributed ratably among the Series A, B, C, and D convertible preferred stockholders.

Election of Board of Directors

The holders of the Series A, B, and C convertible preferred stock are entitled to elect two members, one member and one member, respectively, of the board of directors at each meeting or pursuant to each consent of stockholders for the election of directors. The holders of common stock, voting as a separate class, are entitled to elect two members of the board of directors at each meeting or pursuant to consent of stockholders for the election of directors. Convertible preferred stockholders together with common stockholders, voting together as a single class, are entitled to elect any additional members of the board of directors. The holders of the Series D convertible preferred stock do not have the right, voting as a separate class, to elect any member of the board of directors.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

Warrants

In connection with a loan agreement in 2005, the Company issued warrants to two lenders, SVB and Gold Hill Venture Lending 03, L.P., referred to herein as Gold Hill, to purchase 9,090 shares of the Company s Series A convertible preferred stock at an exercise price of $15.40 per share. The warrants are exercisable immediately and expire 10 years from the issuance date, or March 15, 2015. The value of the warrants was estimated using the Black-Scholes pricing model, and at issuance, the Company initially recorded the relative fair value of the warrants as a debt discount against the related loan payable balance in its balance sheets. The recorded value of the warrants is being amortized to interest expense using the straight-line method over the term of the related loans.

In connection with the Loan Agreement described in Note 8, the Company issued warrants to Oxford Finance LLC and SVB to purchase 10,008 and 20,016 shares of the Company s Series C convertible preferred stock at an exercise price of $11.99 per share during 2011 and 2012, respectively. The warrants are exercisable immediately and expire November 1, 2021. The Company estimated the fair value of these warrants as of the issuance date to be $163,000 and $86,000, which were recorded as a debt discount to the loan and consequently a reduction to the carrying value of the loan. The fair value of the warrants was calculated using the Black-Scholes pricing model, and was based on the contractual term of the warrants of 10 years, a risk-free interest rate of 1.95% to 2.01%, an expected volatility of 60% to 64% and a 0% expected dividend yield.

As of December 31, 2012 and 2013, the following warrants to purchase shares of common stock and convertible preferred stock were outstanding and exercisable:

Warrant Holder	Issue Date	In Connection With	Warrant to Purchase	Shares	Purchase Price	Expiration Date
Oxford Finance LLC	4/30/2012	Loan agreement	Series C	11,676	$ 11.99	11/1/2021
SVB	4/30/2012	Loan agreement	Series C	8,340	$ 11.99	11/1/2021
Oxford Finance LLC	11/1/2011	Loan agreement	Series C	5,838	$ 11.99	11/1/2021
SVB	11/1/2011	Loan agreement	Series C	4,170	$ 11.99	11/1/2021
SVB	3/16/2005	Loan agreement	Series A	3,245	$ 15.40	3/15/2015
Gold Hill	3/16/2005	Loan agreement	Series A	5,845	$ 15.40	3/15/2015
Fred Hutchison Cancer Research Center*	12/7/2004	Collaboration agreement	Common stock	909	$ 1.54	12/7/2014 or IPO, if earlier

* The common stock warrant for 909 shares with an exercise price of $1.54 per share was exercised in January 2014.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

The carrying value of outstanding preferred stock warrants is recorded as a liability as of December 31, 2012 and 2013. The Company will continue to adjust the preferred stock warrant liabilities for changes in the fair value of the warrants until the earlier of the exercise of the warrants, at which time the liability will be reclassified to temporary equity, or the conversion of the underlying preferred stock into common stock, at which time the liability will be reclassified to stockholders deficit, or the expiration of the warrant. The fair value of the preferred stock warrants was estimated to be $237,000 and $244,000 as of December 31, 2012 and 2013, respectively, using the following assumptions:

	Year Ended December 31,			
	2012		2013	
Preferred stock fair value per share	$10.01	$11.99	$10.89	$12.43
Volatility	63%	69%	65%	68%
Risk-free interest rate	0.3%	1.6%	0.2%	2.6%
Remaining contractual term (in years)	2.2	8.8	1.2%	7.8%
Dividend yield	0%		0%	

10. Common Stock

Amended and Restated 2003 Stock Plan

The Company s Amended and Restated 2003 Stock Plan, referred to herein as the 2003 Plan, provides for the granting of incentive and non-statutory stock options to employees, directors and consultants at the discretion of the board of directors.

Incentive stock options may be granted under the 2003 Plan with exercise prices not less than the estimated fair value of common stock, and non-statutory stock options may be granted with an exercise price of not less than 85% of the estimated fair value of the common stock on the date of grant. Options granted under the 2003 Plan to individuals owning over 10% of the total combined voting power of all classes of stock are exercisable up to five years from the date of grant, and the exercise price will not be less than 110% of the estimated fair value of the common stock on the date of grant. 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 determines the fair value of common stock at the date of grant. During 2012 and 2013, the board of directors also granted options to purchase common stock that vest upon the achievement of market-based common stock price targets.

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. The amounts received in exchange for these shares have been recorded as a liability for early exercise of stock options in the accompanying balance sheets and will be reclassified to equity as the shares vest. As of December 31, 2012 and 2013 there were no shares subject to repurchase relating to the early exercise of options.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

Total stock-based compensation recognized in the Company s consolidated statements of operations and comprehensive loss for the years ended December 31, 2012 and 2013, was classified as follows (in thousands):

	Years Ended December 31,	
	2012	2013
Research and development	$ 241	$ 351
General and administrative	588	702
Total	$ 829	$ 1,053

A summary of stock option activity is as follows:

		Outstanding Options	
	Shares Available for grant	Number of Shares	Weighted-Average Exercise Price
Balance, January 1, 2012	271,014	939,843	$ 5.36
Additional shares reserved	227,272		
Options granted	(789,942)	789,942	$ 6.25
Options exercised		(49,934)	$ 3.87
Options forfeited	232,785	(232,785)	$ 6.93
Option expired	106,633	(106,633)	$ 4.85
Balance, December 31, 2012	47,762	1,340,433	$ 5.72
Additional shares reserved	163,636		
Options granted	(168,231)	168,231	$ 5.28
Options exercised		(19,004)	$ 3.65
Options forfeited	75,673	(75,673)	$ 6.21
Option expired	8,437	(8,437)	$ 5.55
Balance, December 31, 2013	127,277	1,405,550	$ 5.68

Among the total outstanding options as of December 31, 2013, options for 1,108,183 shares were exercisable.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

The following table summarizes information about stock options outstanding as of December 31, 2013:

	Options Outstanding		Vested and Exercisable	
Exercise Price	Number of Options	Weighted-Average Remaining Contractual Life (in Years)	Number of Options	Weighted-Average Exercise Price
$0.77	30,666	0.69	30,666	$ 0.77
$1.65	1,453	2.38	1,453	$ 1.65
$2.31	26,816	3.31	26,816	$ 2.31
$2.64	71,851	3.93	71,851	$ 2.64
$3.41	57,725	6.15	57,707	$ 3.41
$4.07	27,074	5.00	27,074	$ 4.07
$4.62	34,220	5.68	34,220	$ 4.62
$4.73	400,207	9.01	75,711	$ 4.73
$6.60	49,243	9.74	2,247	$ 6.60
$6.93	322,947	7.24	194,034	$ 6.93
$7.26	383,348	8.13	120,828	$ 7.26
	1,405,550	7.56	642,607	$ 5.19

As of December 31, 2012:

	Options Outstanding		Vested and Exercisable	
Exercise Price	Number of Options	Weighted-Average Remaining Contractual Life (in Years)	Number of Options	Weighted-Average Exercise Price
$0.77	34,302	1.70	34,302	$ 0.77
$1.65	5,089	2.53	5,089	$ 1.65
$2.31	28,634	4.31	28,634	$ 2.31
$2.64	72,078	4.93	72,078	$ 2.64
$3.41	58,406	7.15	58,161	$ 0.31
$4.07	35,309	6.00	35,069	$ 0.37
$4.62	34,872	6.68	34,542	$ 4.62
$4.73	314,491	9.84	10,844	$ 4.73
$6.93	328,482	8.23	148,541	$ 6.93
$7.26	428,770	9.13	60,040	$ 7.26
	1,340,433	8.30	487,300	$ 4.74

Stock Options Granted to Employees and Non-Employee Directors

During the years ended December 31, 2012 and 2013 the Company granted stock options to employees to purchase 783,125 and 168,231 shares, respectively, of common stock under the 2003 Plan with a weighted-average estimated grant-date fair value of $2.53 and $3.74 per share, respectively. During the years ended December 31, 2012 and 2013, the intrinsic value of stock options exercised was $135,000 and $65,000, respectively. As of December 31, 2012 and 2013, there were total unrecognized compensation costs of $2,122,000 and $1,657,000, respectively, related to these stock options. These costs are expected to be recognized over a weighted-average period of 2.9 and 2.4 years as of December 31, 2012 and 2013, respectively.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

The Company estimated the fair value of stock options using the Black-Scholes option valuation model for options with time-based vesting terms. The Black-Scholes model requires the input of highly complex and subjective assumptions, including (a) the expected term of the award, (b) the expected stock price volatility, (c) the risk-free interest rate and (d) expected dividends. The estimated fair value of these employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of the employee stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31, 2012	2013
Expected term	6.0 6.1 years	5.4 6.1 years
Expected volatility	56% 69%	68% 69%
Risk-free interest rate	0.8% 1.2%	1.2% 1.7%
Expected dividend yield	0%	0%
Expected forfeiture rate	9%	8%

The Company has opted to use the simplified method for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Due to the Company s limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, stages of clinical development, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company s common stock becomes available. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company s stock options. The expected dividend assumption is based on the Company s history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

During the years ended December 31, 2012 and 2013, the Company issued 242,104 and 23,770 shares of options to purchase common stock, respectively, that vests upon the achievement of market-based common stock price targets. The fair value was estimated at the grant date using a Monte-Carlo simulation model. The Monte-Carlo simulation model requires the use of a range of assumptions. The range of risk-free interest rates was 0.4% to 2.2%, expected volatility rates ranged from 65% to 70% and the dividend rate was 0%. The expected life assumption is not used in the Monte-Carlo simulation model, but the output of the model indicated an expected life of 3.4 to 5.5 years. The associated stock-based compensation expense is being recognized on a straight-line basis over the implicit service period derived from that simulation model.

In addition, ASC 718 requires forfeitures to be estimated at the time of the grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those of estimates. Forfeitures were estimated based on management s assessment of industry averages.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

Stock Options Granted to Non-Employees

During the year ended December 31, 2012, the Company granted to non-employees options to purchase 6,817 shares of common stock. The Company did not grant stock options to non-employees during the year ended 2013. Stock-based compensation expense of approximately $10,000 and $35,000 was recorded for the years ended December 31, 2012 and 2013, respectively. The Company measures the estimated fair value of the award each period until the award is fully vested. The fair value of options granted to non-employees during the years ended December 31, 2012 and 2013 was estimated using the Black-Scholes method with the following weighted-average assumptions.

	Year Ended December 31,	
	2012	2013
Remaining contractual term	6.3 9.9 years	6.1 9.9 years
Expected volatility	56% 70%	68% 69%
Risk-free interest rate	0.9% 1.8%	1.1% 2.5%
Expected dividend yield	0%	0%

11. Income Taxes

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	Year ended December 31,	
	2012	2013
Deferred tax assets:		
Net operating loss carry forwards	$ 40,843	$ 45,455
Research and development credit	5,468	6,856
Start-up costs and trademark	1,232	1,113
Depreciation	90	98
Temporary differences	821	1,227
Gross Deferred tax assets	48,454	54,749
Less: valuation allowance	(48,454)	(54,749)
Net deferred tax assets	$	$

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2012 and 2013 is as follows:

	Year ended December 31,	
	2012	**2013**
Statutory tax rate	34.00%	34.00%
State taxes, net of federal benefits	3.98%	7.10%
Stock-based compensation	(1.18)%	(0.81)%
Credits	%	7.65%
True-ups	(2.79)%	0.44%
Other	(0.63)%	(0.45)%
Valuation allowance	(33.38)%	(47.93)%
Effective tax rate	%	%

The Company had federal and state net operating loss carryforwards of approximately $102,551,000 and $102,500,000, respectively, at December 31, 2012, and approximately $114,024,000 and $114,689,000, respectively, at December 31, 2013. The federal and state net operating loss carryforwards are available to reduce future taxable income, if any. If not utilized, the federal and state operating loss carryforwards will begin to expire in various amounts beginning 2023 and 2014, respectively.

The Company also had federal and state research and development credit carryforwards of approximately $3,631,000 and $2,784,000, respectively, at December 31, 2012, and approximately $4,797,000 and $3,120,000, respectively, at December 31, 2013. The federal research and development credit will begin to expire in 2025. State research and development credit can be carried forward indefinitely.

Utilization of the net operating loss carryforwards may be subject to an annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization.

Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by $6,067,000 and $6,295,000 during the years ended December 31, 2012 and 2013, respectively.

Accounting Standards Codification Topic 740-10 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the consolidated financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. ASC 740-10 requires that the Company record an unrecognized tax benefit in its consolidated financial statements based on a two-step analysis. The first step requires determining whether positions are more likely to be sustained upon audit based on the technical merits of the positions. The second step requires measurement of the ultimate liabilities that might result from those positions based on cumulative probabilities of the possible outcomes of settlement with applicable taxing authorities upon audit. No liabilities related to uncertain tax positions are recorded in the consolidated financial statements. The Company may from time to time be assessed interest or penalties by major tax jurisdictions, although there have been no such assessments historically. In the event the Company receives an assessment for interest and/or penalties, it would be classified in the consolidated financial statements as income tax expense. As of December 31, 2013, all tax years in the United States remain open due to the taxing authorities ability to adjust operating loss carry forwards. The Company does not expect any material changes to the unrecognized tax benefits during the next twelve months.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

The Company has recorded no reserves or unrecognized tax benefits for tax positions taken. Since a full valuation allowance has been provided against the Company s deferred tax assets, the effect of any unrecognized tax benefits would be to reduce the gross amount of the deferred tax asset and the corresponding valuation allowance.

12. Employee Benefit Plan

In 2003, the Company adopted a 401(k) plan for its employees whereby eligible employees may contribute up to 100% of their compensation, on a pretax basis, subject to the maximum amount permitted by the Internal Revenue Code. In December 2010, the Company approved a plan to provide matching contributions equal to 50% of employees contributions, up to 6% of annual earnings, starting in January 2011. Company contributions were $196,000 and $152,000 for the years ended December 31, 2012 and 2013, respectively.

13. Related-Party Transactions

In 2010, the Company entered into the 2010 Wellcome Funding Agreement with the Trust, one of the Company s preferred stockholders. As of December 31, 2012, the Company had received $5,594,000 under the 2010 Wellcome Funding Agreement, and recorded the amount as a related-party convertible loan payable. The loan was convertible, at the holder s option, into the Company s next round of preferred stock. In March 2013, the outstanding balance of the 2010 Wellcome Funding Agreement, $5,594,000, was converted into Series D convertible preferred stock at a conversion price that represented a 20% discount to the issue price. Refer to Note 8, Borrowings.

In November 2012, the Company entered into the 2012 Bridge Loan Agreement with certain existing investors. The Company received $2,687,000 under the 2012 Bridge Loan Agreement. Refer to Note 8, Borrowings.

14. Restructuring Charges

In July 2012, the Company initiated a reduction in workforce resulting in an aggregate restructuring charge of approximately $592,000, consisting of severance and benefit payments for terminated employees, of which $367,000 and $225,000 were included as part of research and development and general and administrative expenses, respectively, in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2012. Cash payments related to employee severance were all made by March 31, 2013.

Table of Contents

Index to Financial Statements

Achaogen, Inc.

Notes to Consolidated Financial Statements (continued)

For the year ended December 31, 2013, as a result of the Company ceasing to use certain areas of its leased property, additional restructuring charges of $319,000 were recorded relating to the impairment of certain leasehold improvements of $194,000, net of cash from asset disposal of $2,000, and the recognition of the remaining lease obligation on the subleased ceased-used property of $125,000 in general and administrative expenses. The Company expects to pay accrued facility charges of $274,000, net of cash received from the Company s subtenant, through March 2014. The following table summarizes the accrual balances and utilization by cost type for the restructuring plan (in thousands):

	Employee severance and related benefits	Facilities related and other costs
Beginning at January 1, 2012	$	$
Charges during the period	592	
Cash payments during the period	(541)	
Balance at December 31, 2012	51	
Charges during the period		319
Cash payments during the period	(51)	
Non-cash settlement		(250)
Balance at December 31, 2013	$	$ 69

Table of Contents

Index to Financial Statements