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As filed with the Securities and Exchange Commission on September 22, 2015

Registration No. 333-204905

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2  
to

## FORM S-1 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

### Cerecor Inc.

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>2834</b> (Primary Standard Industrial Classification Code Number)	<b>45-0705648</b> (I.R.S. Employer Identification Number)
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**400 E. Pratt Street, Suite 606  
Baltimore, Maryland 21202  
(410) 522-8707**

(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

**Blake M. Paterson, M.D.  
President and Chief Executive Officer  
Cerecor Inc.**

**400 E. Pratt Street, Suite 606  
Baltimore, Maryland 21202  
(410) 522-8707**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to public:  
As soon as practicable after this registration statement is declared effective.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a  
smaller reporting company)

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED SEPTEMBER 22, 2015.**

**PRELIMINARY PROSPECTUS**

**4,230,769 Shares**



**Common Stock**

This is the initial public offering of our common stock. We are offering 4,230,769 shares of common stock. We currently expect the initial public offering price to be between \$6.00 and \$7.00 per share of common stock.

No public market currently exists for our common stock. Our common stock was approved for listing on the NASDAQ Capital Market under the symbol "CERC."

**Investing in our common stock involves risks. See "Risk Factors" beginning on page 13 of this prospectus.**

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company disclosure requirements for this prospectus and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company" on page 7 of this prospectus.

	<u>Per Share</u>	<u>Total</u>
Initial public offering price	\$	\$
Underwriting discounts and commissions(1)	\$	\$
Proceeds to Cerecor (before expenses)	\$	\$

(1) We refer you to "Underwriting" beginning on page 189 of this prospectus for additional information regarding total underwriter compensation.

We have granted a 45-day option to the underwriters to purchase up to 634,615 additional shares of common stock to cover over-allotments, if any.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2015.

**Maxim Group LLC**

**Laidlaw & Company (UK) Ltd.**

Prospectus dated \_\_\_\_\_, 2015

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*Neither we nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any free writing prospectus we have prepared. If anyone provides you with different or inconsistent information, you should not rely on it. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where or to any person to whom the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.*

*Through and including \_\_\_\_\_, 2015 (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.*

*This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.*

*For investors outside the United States: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.*

## PROSPECTUS SUMMARY

*The following summary highlights information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information that may be important to you. You should read and carefully consider the following summary together with the entire prospectus, including our financial statements and the notes thereto appearing elsewhere in this prospectus and the matters discussed in the sections in this prospectus entitled "Risk Factors," "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding to invest in our common stock. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results could differ materially from those anticipated in such forward-looking statements as a result of certain factors, including those discussed in the "Risk Factors" section and other sections of this prospectus.*

*Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to "Cerecor," "the company," "we," "us" and "our" refer to Cerecor Inc.*

### Overview

We are a clinical-stage biopharmaceutical company with the goal of becoming a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. We have a portfolio of clinical and preclinical compounds that we believe are best-in-class due to their unique mechanism of action and where human proof of concept has been established for the compound or the target. We are currently pursuing the regulatory approval of three product candidates: CERC-301, CERC-501 and CERC-406.

CERC-301 is currently in Phase 2 development as an oral, adjunctive treatment of patients with major depressive disorder, or MDD, who are failing to achieve an adequate response to their current antidepressant treatment and are severely depressed. We received fast track designation by the United States Food and Drug Administration, or FDA, in November 2013 for CERC-301 for the treatment of MDD. CERC-301 belongs to a class of compounds known as antagonists, or inhibitors, of the N-methyl-D-aspartate, or NMDA, receptor, a receptor subtype of the glutamate neurotransmitter system that is responsible for controlling neurological adaptation. We believe CERC-301 will be a "first-in-class" medication that will cause a significant reduction in depression symptoms in a matter of days, as compared to weeks or months with conventional therapies, because it selectively blocks the NMDA receptor subunit 2B, or NR2B, which we believe provides rapid and significant antidepressant activity without the adverse side effect profile of non-selective NMDA receptor antagonists. We are also currently developing CERC-501, which is in Phase 2 development. We intend to first develop CERC-501 for adjunctive treatment of MDD and for substance use disorders (e.g., nicotine, alcohol, and/or cocaine). If we receive approval for CERC-501 for adjunctive treatment of MDD and for substance use disorders, we plan to further develop CERC-501 for the concurrent treatment of MDD and substance use disorders, or co-occurring disorders. CERC-501 was acquired in February 2015, and is a potent and selective kappa opioid receptor, or KOR, antagonist. KORs are believed to play key roles in modulating stress, mood and addictive behaviors, which form the basis of co-occurring disorders. We are preparing to initiate a clinical study to evaluate the effect of CERC-501 on aspects of tobacco withdrawal and reinstatement in the first half of 2016. In addition, we are considering conducting a Phase 2 clinical study in inadequately treated subjects with MDD currently on antidepressants, with an initiation date in the second half of 2016. Thereafter, we intend to pursue additional studies focused on substance use disorders, the adjunctive treatment of MDD and, depending on marketing approval, the treatment of co-occurring disorders. CERC-406 is our preclinical lead candidate from our proprietary platform of compounds that inhibit catechol-O-methyltransferase, or COMT, within the brain, which we refer to as our COMTi platform. We anticipate developing CERC-406 for the treatment of residual cognitive impairment symptoms in patients with MDD.

Members of our management team have extensive pharmaceutical product development and commercialization experience and they have played key roles in the development or commercialization of Prozac®, Zyprexa®, Lyrica®, Cymbalta®, Neurontin® and Abilify®, each of which is a neuroscience product that has generated over \$1.0 billion of annual revenues. Collectively, our officers and directors have contributed to the submission of numerous Investigational New Drug Applications, or INDs, and nine New Drug Applications, or NDAs, to the FDA. Leveraging the experience of our management team, within the last 24 months we obtained IND clearance and received fast track designation for CERC-301 from the FDA, completed two clinical trials of CERC-301, selected CERC-406 as our preclinical lead candidate from our COMTi platform and, most recently, broadened our clinical pipeline by in-licensing CERC-501.

### Product Candidates and Platform

#### Product Pipeline

The following table summarizes key information about our three product candidates and further detail regarding each product candidate is provided under the heading "Business" in this prospectus:

Product Candidate / Platform	Potential Indication(s)	Stage of Development	Anticipated Milestones
<b>CERC-301</b>	Adjunctive treatment of MDD with rapid onset	Phase 2	Data in the second half of 2016
<b>CERC-501</b>	Substance use disorders Adjunctive treatment of MDD Co-occurring disorders	Phase 2	Data in the second half of 2016
<b>CERC-406</b>	Residual cognitive impairment symptoms in MDD	Preclinical	IND submission anticipated in the first half of 2017

#### CERC-301

Depression is one of the most common serious medical and psychiatric disorders, with more than 150 million adults worldwide suffering from MDD at any given time, according to a 2003 report by the World Health Organization, or WHO, titled *Investing in Mental Health*. According to the IMS Institute for Healthcare Informatics' 2012 report titled *The Use of Medicines in the United States: Review of 2011*, over 264 million prescriptions totaling \$11 billion were filled for depression in the United States in 2011. Nevertheless, many patients undergoing treatment with currently available pharmacologic MDD therapies experience delayed onset of therapeutic response, high rates of sub-optimal response, low rates of remission and treatment-limiting side effects.

CERC-301, which we have licensed from Merck & Co., Inc. and its affiliates, or Merck, belongs to a class of compounds known as antagonists of the NMDA receptor. Research on ketamine, such as *A Randomized Trial of an N-methyl-D-aspartate Antagonist in Treatment-Resistant Major Depression* study conducted by Dr. Carlos A. Zarate, Jr. and others, has provided evidence that NMDA receptor antagonists can have significant antidepressant activity within 24 hours of administration and that this effect may be associated with a biomarker of neuronal growth. We believe efficacy of the class is further supported by the off-label use of ketamine throughout the United States as a rapid-acting antidepressant in treatment resistant bipolar depression and MDD. Ketamine is an anesthetic that is a non-selective NMDA receptor antagonist, is not approved as an antidepressant and has several significant limitations, including the need for repeated intravenous administration in a clinic and undesirable side effects such as increases in blood pressure and significant psychotomimetic effects, including intoxication and hallucinations.

We believe CERC-301 has potential competitive advantages over current treatments because it is orally administered and it selectively blocks the NR2B. An August 2012 study published by the National Institute of Mental Health, or NIMH, provides support for the potential competitive advantages of CERC-301 because it demonstrated that CERC-301 had a rapid onset of antidepressant effect in subjects with treatment resistant depression along with an increase in a biomarker commonly seen with an antidepressant effect, without many of the side effects commonly seen in non-selective NMDA receptor antagonists.

In 2014 we completed an exploratory inpatient pharmacokinetic, or PK, and pharmacodynamics, or PD, study in healthy volunteers, which we refer to as the PK/PD study, and a Phase 2 outpatient efficacy study for the adjunctive treatment of patients with severe MDD who had recently experienced suicidal ideation. The PK/PD study provided evidence of safety and tolerability at daily doses up to 20 mg for seven days, along with apparent increases in the biomarker. In the Phase 2 study, CERC-301 was administered daily at a dose of 8 mg for 28 days, as an adjunctive treatment to subjects' current medications. While CERC-301 was well tolerated, there were no biomarker changes and the study failed to demonstrate any significant antidepressant effect, which we believe suggests that drug exposure was inadequate. Given the safety and tolerability of higher doses observed in the PK/PD study, we initiated a Phase 2 study utilizing higher doses and a revised dosing regimen, Clin301-203, in the third quarter of 2015 with results becoming available in the second half of 2016.

Upon completion of Clin301-203, and dependent upon study results, we plan to conduct a multi-dose, six week Phase 2b study of CERC-301 as adjunctive treatment in subjects with MDD who are currently experiencing a severe depressive episode despite stable ongoing treatment with a serotonin reuptake inhibitor, or SSRI, or serotonin norepinephrine reuptake inhibitor, or SNRI. We expect to initiate this dose ranging study in the first half of 2017. Thereafter we plan to engage the FDA in an end-of-phase 2 meeting to align plans and activities for potential regulatory approval which would include Phase 3 clinical studies, non-clinical NDA enabling studies and manufacturing activities.

### **CERC-501**

Numerous studies have shown that many patients do not respond to their initial antidepressant therapy. For example, according to a 2006 report titled *Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR-D Report*, or the STAR-D Report, 51.4% of patients failed to respond, defined as achieving a 50% reduction in symptoms, and only 36.8% became symptom free, or achieved remission, after their initial 12-week treatment course with monoamine antidepressants. As such, physicians commonly will switch patients' antidepressants to manage depression, and patients may require two or three courses of treatment, before achieving satisfactory relief. The depression may persist following a course of treatment and additional medications may need to be used adjunctively. These adjunctive agents may include atypical antipsychotics, like aripiprazole and quetiapine, or other agents such as bupropion and lithium.

Drug abuse is a major public health problem that impacts society on multiple levels. According to *Results from the 2013 National Survey on Drug Use and Health*, a survey conducted by the Substance Abuse and Mental Health Services Administration, in 2013, an estimated 21.6 million persons in the United States aged 12 or older (8.2 percent of the population) were classified with substance dependence or abuse in the past year based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition. Of these, 2.6 million were classified with dependence or abuse of both alcohol and illicit drugs, 4.3 million had dependence or abuse of illicit drugs but not alcohol, and 14.7 million had dependence or abuse of alcohol but not illicit drugs. Illicit drugs include marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants, or prescription-type psychotherapeutics (pain relievers, tranquilizers, stimulants, and sedatives) used nonmedically. Furthermore, in 2013, heavy drinking was reported by 6.3 percent of the United States population aged 12 or older, or 16.5 million people. Cigarette smoking and exposure to tobacco smoke are the

leading causes of preventable disease and death in the United States, resulting in more than 480,000 premature deaths and \$289 billion in direct health care expenditures and productivity losses each year. In 2013, 55.8 million persons (21.3 percent of the population) were current cigarette smokers. Despite progress over the past several decades, millions of adults still smoke cigarettes, the most commonly used tobacco product in the United States, and this continues to be major public health problem.

Mood, anxiety and substance use disorders, such as nicotine and alcohol dependence, are highly co-morbid in humans. Greater than 150 million adults worldwide suffer from MDD at any given time, according to a 2003 report by WHO titled *Investing In Mental Health*, and, according to the United States National Comorbidity Survey Replication, or NCS-R, more than 16 million adults in the United States, which represents approximately 6.7% of its entire adult population, will suffer from a MDD episode in a 12 month period. One common link between the co-occurrence of depression and substance use disorders may be stress. Sustained stressful experiences can induce despair and increase the risk of clinical depression and substance use. Substance use often provides relief from stress, such that the substance of abuse often becomes a potent behavioral reinforcer. Present pharmacologic treatments for co-occurring psychiatric and substance use disorders, or co-occurring disorders, consist either of treatment for the psychiatric disorder or the treatment for the addiction, but not the treatment of the underlying connection between the two. Therefore, we believe a tremendous need exists for pharmacotherapies effective in the treatment of co-occurring disorders.

In February 2015, we acquired rights to CERC-501, through an exclusive, worldwide, license from Eli Lilly and Company. CERC-501 is a high-binding, selective antagonist of KORs in the brain. KORs are localized in areas of the brain which effect reward and stress and are believed to impact mood, stress and addictive disorders. Preclinical data to date support the emerging consensus that selective kappa opioid antagonists have antidepressant and anti-anxiety like effects, reduce addictive substance consumption, and reduce behaviors and signs of drug withdrawal. As these studies demonstrate efficacy in animal models of both mood and addictive disorders, we believe that these studies provide the basis for the use of KOR antagonists in mood and substance use disorders and have the potential to reduce co-morbid mood disorders. We believe that the rationale for CERC-501 as an adjunctive treatment in MDD is supported by the reported Phase 2 results of Alkermes plc's, or Alkermes, investigational drug ALKS-5461, which is believed to be acting as a functional kappa antagonist. Alkermes has reported positive Phase 2 results for ALKS-5461 as an adjunctive antidepressant in MDD subjects and has initiated a Phase 3 development program. According to a press release by Alkermes, "ALKS-5461 had an onset of effect, as measured by MADRS, evident after one week of treatment." This suggests a rapid response to antidepressant treatment but not as rapid as what has been reported in the ketamine depression clinical trials.

For approximately the next 24 months, we expect to evaluate the potential human utility of CERC-501 in smoking dependence, depression, cocaine dependence, and anhedonia and mood disorders. The depression and anhedonia and mood studies are being performed in academic centers, under the auspices of the NIMH. We will be conducting the smoking study, which we refer to as Clin501-201. In addition, we are considering conducting a Phase 2 clinical study in inadequately treated subjects with MDD currently on antidepressants, with an initiation date in the second half of 2016. Thereafter, we intend to pursue additional studies focused on substance use disorders, the adjunctive treatment of MDD and, depending on marketing approval, the treatment of co-occurring disorders. We believe competitively positioning CERC-501 as a treatment of substance use disorders, a once-a-day, oral adjunctive treatment of MDD, and, depending on marketing approval, a treatment for co-occurring disorders it has the potential to generate widespread market acceptance. We further believe that, if CERC-501 has the ability to provide rapid onset of antidepressant effect, the market opportunity will be further expanded.



### **COMTi Platform**

In March 2013, we acquired rights to our COMTi platform by means of an exclusive, worldwide license from Merck. Our COMTi platform consists of a library of approximately 1,800 compounds that we believe may penetrate the nervous system and preferentially inhibit COMT in the brain. COMT is an enzyme that breaks down dopamine and its inhibition has demonstrated applicability in treating certain neuropsychiatric conditions, including schizophrenia, Parkinson's disease and pathological gambling. We believe potent, brain-specific COMT inhibitors will selectively increase dopamine levels in the prefrontal cortex, which is the region of the brain that is responsible for verbal learning, working memory, attention tasks and decision making, thereby improving executive function. Moreover, our development efforts are specifically focused on a new generation of potent COMT inhibitors that we believe avoid off-target toxicity and side effects, such as liver toxicity and diarrhea, which are often seen with the previous generation of inhibitors, such as tolcapone and entacapone.

#### *CERC-406*

In January 2015, we selected CERC-406 as our first preclinical lead candidate from the COMTi platform. In 2015 and 2016, we intend to establish the data set necessary to select additional preclinical lead candidates and to initiate programs for treatment of various conditions where impaired executive function is a core symptom. These programs will target the improvement of working memory and executive function, which are key components of cognition.

CERC-406 is a small molecule, that research indicates is a selective COMT inhibitor with low inhibitory activity on peripheral COMT. We anticipate developing CERC-406 as a "first-in-class," oral adjunctive medication for patients with residual cognitive impairment symptoms suffering from MDD. We selected CERC-406 as our preclinical lead candidate from our COMTi platform because in preclinical testing it demonstrated lower potential of peripheral, off target side effects, rapid absorption and bioavailability, good brain penetration and a favorable dose-dependent biomarker profile in rats. CERC-406 has also demonstrated off-rate on brain COMT that is slower than tolcapone, implying good duration of effect. Finally, CERC-406 has demonstrated a favorable safety profile in all studies conducted to date. In preliminary studies it appears that CERC-406 may have favorable drug distribution and metabolism properties, suggesting that it has the potential to be administered orally on a once or twice daily basis. We plan to file an IND for CERC-406 in the first half of 2017 and, upon acceptance of this IND filing, we will commence Phase 1 studies to examine human safety, tolerability and pharmacokinetics that will determine suitability for further development.

### **Our Strategy**

Our goal is to be a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. Our strategic objectives include:

- rapidly advancing the clinical development of CERC-301;
- rapidly advancing the clinical development of CERC-501;
- advancing CERC-406 into IND-enabling studies;
- using our COMTi platform to build a pipeline of future product candidates for conditions where impaired executive function is a core symptom;
- establishing collaborations to maximize value; and
- expanding our product candidate portfolio through in-licensing and strategic acquisitions.

## **Management**

Members of our management team have extensive pharmaceutical product development and commercialization experience and they have played key roles in the development or commercialization of Prozac®, Zyprexa®, Lyrica®, Cymbalta®, Neurontin® and Abilify®, each of which is a neuroscience product that has generated over \$1.0 billion of annual revenues. Collectively, our directors and officers have contributed to the submission of numerous Investigational New Drug Applications, or INDs, and nine NDAs to the FDA. Leveraging the experience of our management team, we obtained IND clearance and received fast track designation for CERC-301 from the FDA, completed two clinical trials of CERC-301, selected CERC-406 as the initial candidate from our COMTi platform and, most recently, broadened our clinical pipeline by in-licensing CERC-501.

## **Risks Associated with Our Business**

Our ability to implement our business strategy is subject to numerous risks and uncertainties that you should be aware of before making an investment decision. As a clinical-stage biopharmaceutical company, we face many risks inherent in our business and our industry generally. You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors," prior to making an investment in our common stock. These risks include, among others, the following:

- we have not received, and we may not receive, regulatory approval for CERC-301, CERC-501 or any other product candidates;
- we have no source of predictable revenue and have incurred significant operating losses since inception which has raised substantial doubt regarding our ability to continue as a going concern and has resulted in our independent registered public accounting firm including an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2014 with respect to our ability to continue as a going concern;
- we may never become profitable and we may incur substantial and increasing net losses for the foreseeable future as we continue development of, seek marketing approvals for and begin to commercialize our product candidates and, as of June 30, 2015, we had an accumulated deficit of \$49.2 million;
- we will need to obtain additional funding to continue operations, which may not be available to us on acceptable terms, or at all;
- our success is primarily dependent on the successful development, marketing approval and commercialization of our product candidates, all of which are in early development;
- if clinical trials of our product candidates fail to demonstrate safety and efficacy or do not otherwise produce positive results, such as the failure of our discontinued product candidate, FP01, to meet the primary endpoint in two Phase 2 studies and the failure of CERC-301 to meet the primary endpoint in one Phase 2 study, we may be unable to obtain marketing approvals and commercialize our product candidates;
- we are subject to marketing approval processes that are lengthy, expensive, time-consuming and unpredictable;
- the third-party coverage and reimbursement status of our product candidates is uncertain, and failure to obtain or maintain adequate coverage and reimbursement for products could limit our ability to market those products and decrease our ability to generate revenue;

- we must obtain state manufacturer and/or wholesaler licenses for the sale and distribution of our products into each state, and if we are delayed in obtaining these state licenses, or denied the licenses, even with FDA approval, we would not be able to sell or ship product into that state;
- we may be unable to recruit or retain key employees, including our senior management team, which may prevent us from successfully developing and commercializing our product candidates or otherwise implementing our business plan;
- we may not be able to obtain and enforce patent rights or other intellectual property rights that cover our product candidates and that are of sufficient breadth to prevent third parties from competing against us; and
- we depend on the performance of third parties, including contract research organizations and third-party manufacturers.

### **Our Corporate Information**

We were incorporated as Ceregen Corporation in Delaware on January 31, 2011, and we subsequently changed our name to Cerecor Inc. Our principal executive offices are located at 400 E. Pratt Street, Suite 606, Baltimore, Maryland 21202 and our telephone number is (410) 522-8707. Our website address is [www.cerecor.com](http://www.cerecor.com). The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

The trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies or products.

### **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 of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; 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 may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenues, have more than \$700.0 million in market value of our capital

stock held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, 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. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

## THE OFFERING

Common stock offered	4,230,769 shares
Common stock to be outstanding immediately following this offering	8,860,912 shares
Over-allotment option	We have granted to the underwriters the option, exercisable for 45 days from the date of this prospectus, to purchase up to 634,615 additional shares of common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately \$22.7 million, or approximately \$26.5 million if the underwriters exercise their over-allotment option in full, based on an assumed initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the costs of Phase 2 clinical development of CERC-301 and CERC-501, preclinical research for CERC-406, research and development to build our COMTi platform and potential in licensing or other acquisitions and for working capital and general corporate purposes. See "Use of Proceeds."
Risk Factors	You should read the "Risk Factors" section of this prospectus beginning on page 13 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Approved NASDAQ Capital Market symbol	"CERC"

The number of shares of our common stock to be outstanding after this offering is based on 649,721 shares of our common stock outstanding as of June 30, 2015 and includes 3,980,422 shares of our common stock issuable upon the automatic conversion of all outstanding shares of our convertible preferred stock.

The number of shares of our common stock to be outstanding immediately following this offering excludes:

- 510,884 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2015, at a weighted-average exercise price of \$8.88 per share;
- 490,756 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2015 at a weighted-average exercise price of \$26.32 per share, which warrants are expected to remain outstanding upon the closing of this offering in accordance with their terms;
- 166,718 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2015 at a weighted-average exercise price of \$8.40 per share, which warrants will expire upon the closing of this offering in accordance with their terms, unless exercised prior thereto;
- 22,328 shares of our common stock issuable upon the exercise of the warrant outstanding as of June 30, 2015 at an exercise price of \$8.40 per share, which warrant is exercisable to purchase

shares of Series B convertible preferred stock prior to the completion of this offering, and which warrant is expected to remain outstanding upon the closing of this offering;

- 42,307 shares of our common stock issuable upon the exercise of the warrants issued in connection with this offering to the underwriters at an exercise price of \$7.48, assuming an initial public offering price of \$6.50 per share, which is the midpoint of this price range set forth on the cover page of this prospectus and a total of 4,230,769 shares of our common stock are sold in this offering;
- 254,236 shares of our common stock available for future issuance under our 2011 Stock Incentive Plan as of June 30, 2015, which upon effectiveness of our 2015 Omnibus Incentive Compensation Plan will be available for issuance under our 2015 Omnibus Incentive Compensation Plan; and
- 890,815 shares of our common stock available for future issuance under our 2015 Omnibus Incentive Compensation Plan, which will become effective upon the business day immediately preceding the date on which the registration statement is declared effective.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- a 1 for 28 reverse stock split of our common stock effected on September 1, 2015;
- no exercise of the outstanding options or warrants described above;
- the warrants outstanding as of June 30, 2015 to purchase an aggregate of 490,756 shares of our common stock at a weighted-average exercise price of \$26.32 per share, which warrants will remain outstanding upon the closing of this offering in accordance with their terms;
- the warrant outstanding as of June 30, 2015 to purchase 625,208 shares of Series B preferred stock has become, in accordance with its terms, a warrant to purchase 22,328 shares of common stock at an exercise price of \$8.40 per share upon the closing of this offering;
- no exercise by the underwriters of their option to purchase up to 634,615 additional shares of our common stock to cover over-allotments;
- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,980,422;
- the amendment and restatement of our certificate of incorporation and bylaws upon the closing of this offering; and
- on a pro forma basis to give effect to the reclassification of approximately \$1.5 million related to the Investor rights obligation and warrant liability from liabilities to permanent equity upon the closing of this offering.

## SUMMARY FINANCIAL DATA

The following tables set forth our summary financial data for the periods indicated. The following summary financial data for the years ended December 31, 2013 and 2014 are derived from our audited financial statements appearing elsewhere in this prospectus. The following summary financial data for the six-month periods ended June 30, 2014 and 2015 and the selected balance sheet data as of June 30, 2015 are derived from our unaudited financial statements appearing elsewhere in this prospectus.

This summary financial data should be read together with the historical financial statements and related notes to those statements, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations," which are included elsewhere in this prospectus. See note 3 to our audited financial statements appearing elsewhere in this prospectus for information regarding computation of basic and diluted net loss per share of common stock, unaudited pro forma basic and diluted net loss per share of common stock and the unaudited pro forma weighted average basic and diluted common shares outstanding used in computing pro forma basic and diluted net loss per common share.

	Years Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
<b>Operating expenses:</b>				
Research and development	\$ 8,914,084	\$ 12,240,535	\$ 5,610,764	\$ 3,598,606
General and administrative	4,020,364	4,875,030	1,673,573	1,776,817
Total operating expenses	12,934,448	17,115,565	7,284,337	5,375,423
Loss from operations	(12,934,448)	(17,115,565)	(7,284,337)	(5,375,423)
<b>Other income (expense):</b>				
Change in fair value of warrant liabilities and investor rights obligation	(121,115)	2,266,161	385,990	(337,739)
Interest income (expense), net	10,555	(1,206,187)	(794,038)	(437,302)
Total other income (expense):	(110,560)	1,059,974	(408,048)	(775,041)
Net loss	(13,045,008)	(16,055,591)	(7,692,385)	(6,150,464)
Net loss attributable to common stockholders	\$ (13,126,972)	\$ (3,521,153)	\$ (7,692,385)	\$ (6,150,464)
Net loss per share of common stock, basic and diluted	\$ (20.72)	\$ (5.48)	\$ (12.10)	\$ (9.47)
Weighted-average shares of common stock outstanding, basic and diluted	633,669	642,052	635,714	649,721
Pro forma net loss per share of common stock—basic and diluted (unaudited)		\$ (1.01)		\$ (1.33)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)		3,501,768		4,630,143

The following table presents our summary balance sheet data:

- on an actual basis as of June 30, 2015;
- on a pro forma basis to give effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,980,422 shares of our common stock and (ii) the reclassification of approximately \$1.5 million related to the investor rights obligation and warrant liability from liabilities to permanent equity upon the closing of this offering; and

- on a pro forma as adjusted basis to give further effect to our sale of 4,230,769 shares of common stock in this offering at an assumed initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information presented in the summary balance sheet data is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of cash and cash equivalents, total assets and total stockholders' equity (deficit) on a pro forma as adjusted basis by approximately \$3.9 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase or decrease of 1.0 million shares offered by us at the assumed initial public offering price would increase or decrease each of cash and cash equivalents, total assets and total stockholders' equity (deficit) on a pro forma as adjusted basis by approximately \$5.9 million.

	As of June 30, 2015		
	Actual	Pro forma (unaudited)	Pro forma as adjusted (unaudited)
Cash and cash equivalents	\$ 6,143	\$ 6,143	\$ 28,854
Total assets	7,582	7,582	30,293
Total liabilities	11,426	9,906	9,906
Convertible preferred stock	28,346	—	—
Total stockholders' equity (deficit)	(32,189)	(2,324)	20,387



## RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, results of operations, financial condition, cash flows and future growth. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.*

### **Risks Related to Our Financial Position and Capital Needs**

*We have incurred significant net losses in every period since our inception and anticipate that we will continue to incur net losses in the future.*

We are a clinical-stage biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate an adequate effect or acceptable safety profile, gain marketing approval and become commercially viable. To date, we have financed our operations primarily through private placements of our common and convertible preferred stock and convertible debt. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses in each period since our inception in 2011. For the years ended December 31, 2013 and 2014, and the six-month period ended June 30, 2015, we reported a net loss of \$13.0 million, \$16.1 million and \$6.2 million, respectively. As of June 30, 2015, we had an accumulated deficit of \$49.2 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development program and from general and administrative costs associated with our operations.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek marketing approvals for, our product candidates. If we do not successfully develop and obtain marketing approval for our product candidates and effectively market and sell any product candidates that are approved, we may never generate product sales. Even if we do generate product sales, we may never achieve or sustain profitability on an annual basis. Furthermore, following this offering, we expect to incur additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

*We currently have no source of product revenue and may never become profitable.*

Our ability to generate product revenue and achieve profitability depends on our ability, alone or with partners, to successfully complete the development of, and obtain the marketing approvals necessary to commercialize, our product candidates. To date, we have not generated any revenues from commercialization of our product candidates and we do not know when, or if, we will generate any such revenues. Our ability to generate product revenue and ultimately become profitable depends upon our ability, alone or partnered, to successfully commercialize products, including any of our current product candidates or other product candidates that we may develop, in-license or acquire in the future. We do not anticipate generating revenue from the sale of products for the foreseeable future.

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Our ability to generate future product revenue from our current or future product candidates also depends on a number of additional factors, including our ability to:

- successfully complete research and clinical development of current and future product candidates;
- seek and obtain marketing approvals for product candidates for which we complete clinical trials;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize product candidates for which we obtain marketing approval, if any, and if launched independently or under a co-promotion agreement, successfully establish a sales force, marketing and distribution infrastructure;
- identify and validate new product candidates;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for our or our partners' products, if any;
- implement additional internal systems and infrastructure as needed;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- address any competing technological and market developments;
- establish, maintain and protect our intellectual property rights, including patents, trade secrets and know-how; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biopharmaceutical product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses. In addition, our expenses could increase beyond expectations if we decide to or are required by the United States Food and Drug Administration, or FDA, or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing these products, which may not gain market acceptance or achieve commercial success.

Even if we generate revenues from the sale of any of our products that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or do not sustain profitability on a continuing basis, then the market price of our common stock could be depressed and we may be unable to raise capital, expand our business, diversify our product offerings, including obtaining new product candidates, or otherwise continue our operations at planned levels and be forced to reduce our operations. We do not know if or when we will achieve or maintain profitability.

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***Even if this offering is successful, we will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.***

As a research and development company, our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into clinical trials or obtain and advance additional product candidates. We estimate that the net proceeds from this offering will be approximately \$22.7 million, based on an assumed initial public offering price of \$6.50, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will fund our projected operating requirements into the fourth quarter of 2016. See "Use of Proceeds." However, circumstances may cause us to consume capital more rapidly than we currently anticipate. For example, as we move our product candidates CERC-301 and CERC-501 through clinical trials, we may fail to meet our primary or secondary endpoints, which occurred for our first Phase 2 study for CERC-301, requiring us to complete more trials than originally expected or we may discover serious adverse side effects. Moreover, as we move our COMT inhibitor, or COMTi, product candidates, such as CERC-406, through preclinical studies, submit Investigational New Drug Applications, or INDs, and initiate clinical trials, we may produce adverse results requiring us to find new product candidates. Any of these events may increase our development costs more than we expect. We may need to raise additional funds or otherwise obtain funding through collaborations if we choose to initiate additional clinical trials for product candidates. In any event, we will require additional capital to obtain marketing approval for, and to commercialize, future product candidates.

If we need to secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

- significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or cease operations altogether;
- seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves.

If we need to conduct additional fundraising activities and we do not raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, financial condition, results of operations and prospects.

Our forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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Our future funding requirements, both short and long term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical and clinical studies for our product candidates and future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than we currently expect to perform;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing; and
- the cost of establishing sales, marketing and distribution capabilities for our product candidates for which we may receive marketing approval and that we determine to commercialize ourselves or in collaboration with our partners.

If a lack of available capital results in our inability to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

### ***Raising additional capital may cause dilution to our existing stockholders or restrict our operations.***

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, such raises could result in dilution to our existing stockholders and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change federal net operating loss carryforwards, or NOLs, and other pre-change federal tax attributes (such as research tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of the closing of this offering and subsequent shifts in our stock ownership. State NOL carryforwards may be similarly or more stringently limited. As a result, if we earn net taxable income,

our ability to use our pre-change NOLs to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

***In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.***

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and revenues and related disclosure of contingent assets and liabilities. For example, we estimate clinical trial costs incurred using subject data and information from our contract research organizations, or CROs. If we underestimate or overestimate these expenses, adjustments to expenses may be necessary in future periods. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We commenced active operations in the second quarter of 2011 and our operations to date have included organizing and staffing our company, business planning, raising capital and developing our product candidates and platform. Two of our product candidates, CERC-301 and CERC-501, are currently in Phase 2 development and we anticipate receipt of data in the second half of 2016 from the Phase 2 studies we are initiating for each product candidate. We have not yet, however, demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as an early stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be able to successfully complete such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***We may engage in in-licensing acquisitions or other strategic transactions that could impact our liquidity, increase our expenses and divert a significant amount of our management's time.***

Since inception, we have in-licensed each of our product candidates and our COMTi platform. From time to time we may consider additional in-licensing of products and other strategic transactions, such as acquisitions of companies, asset purchases and out-licensing of product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including strategic partnerships, collaborations, joint ventures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and

financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or other counterparties of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

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

Our recurring operating losses and negative cash flows from operations 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 financial statements as of and for the year ended December 31, 2014 with respect to this uncertainty. We have no current source of revenues to sustain our present activities, and we do not expect to generate revenues until, and unless, the FDA or other regulatory agencies approve our product candidates and we successfully commercialize any such product candidates. 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.

#### **Risks Related to Our Business and Industry**

***We are heavily dependent on the success of our product candidates, CERC-301 and CERC-501. If we fail to obtain marketing approval for and commercialize CERC-301 and CERC-501, or experience delays in doing so, our business will be materially harmed.***

We intend to invest a significant portion of our efforts and financial resources in the development of our product candidates, CERC-301 and CERC-501; and we anticipate that we will allocate the majority of the proceeds of this offering toward their development. To date we have not marketed, distributed or sold any products. Our ability to generate revenues is substantially dependent on the development and commercialization of CERC-301 and CERC-501. If our clinical development for CERC-301 is successful, we plan to submit an NDA seeking approval to commercialize CERC-301 as an oral, adjunctive treatment of patients with MDD who are failing to achieve an adequate response to their current antidepressant treatment and, are severely depressed. If our clinical development for CERC-501 is successful, we plan to submit an NDA seeking approval to commercialize CERC-501 for adjunctive treatment of major depressive disorder, or MDD, and for substance use disorders (e.g., nicotine, alcohol, and/or cocaine). If we receive approval for CERC-501 for adjunctive treatment of MDD and for substance use disorders, we plan to further develop CERC-501 for the concurrent treatment of MDD and substance use disorders, or co-occurring disorders. We cannot commercialize

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our product candidates prior to obtaining marketing approval from the FDA. Each of CERC-301 and CERC-501 is susceptible to the risks of failure inherent at any stage of drug development, including the appearance of unexpected adverse events, the failure to demonstrate efficacy and the FDA's determination that such candidate is not approvable. If we do not receive marketing approval for and commercialize either CERC-301 or CERC-501, we will not be able to generate product revenues in the foreseeable future, or at all.

If, following submission, our NDA for either product candidate is not accepted for substantive review or approved, the FDA may require that we conduct additional clinical or preclinical trials, manufacture additional validation batches or develop additional analytical test methods before it will reconsider our application for such product candidate. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional required trials that we perform and complete to be sufficient.

Even if we believe that the data from our clinical trials and analytical testing methods support marketing approval of CERC-301 or CERC-501 in the United States, the FDA may not agree with our analysis and approve our NDA. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing CERC-301 or CERC-501, generating revenues and achieving profitability.

***Only two of our product candidates that we intend to commercialize are in clinical development. Preclinical testing of other product candidates may not lead to them advancing into clinical trials. If we do not successfully complete preclinical testing of our product candidates or experience significant delays in doing so, our business will be materially harmed.***

We have invested a significant portion of our efforts and financial resources in the identification and preclinical and clinical development of product candidates. For example, a significant portion of our financial resources were dedicated to the development of FP01, which we no longer plan to develop. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on our ability to advance our preclinical product candidates into clinical development and successfully complete preclinical testing of our clinical stage product candidates. The outcome of preclinical studies may not predict the success of clinical trials. Preclinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed in clinical development. Our inability to successfully complete preclinical development could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales.

***If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

Before obtaining required approvals from regulatory authorities for the sale of future product candidates, we alone, or with a partner, must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. For example, the Clin301-201 study for CERC-301 failed to meet its primary endpoint and, in addition, our discontinued product candidate FP01 failed to meet its primary endpoint in two Phase 2 clinical studies. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology

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industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Our product candidates will require additional clinical and preclinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply on our own or from a third party, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales. We do not know whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates would be adversely impacted.

***If we experience delays in clinical testing, we will be delayed in obtaining regulatory approvals and commercializing our product candidates, our costs may increase and our business may be harmed.***

We do not know whether any clinical trials will begin as planned, whether the design will be revised prior to or during conduct of the study, completed on schedule or conducted at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Events which may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching an agreement with or failure in obtaining authorization from the FDA, other regulatory authorities or institutional review boards, or IRBs, to commence or amend a clinical trial;
- imposition of a clinical hold or trial termination following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities, or due to concerns about trial design, or a decision by the FDA, other regulatory authorities, IRBs or the company, or recommendation by a data safety monitoring board, to place the trial on hold or otherwise suspend or terminate clinical trials at any time for safety issues or for any other reason;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
- failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- failure to enter into agreements with third parties to obtain the results of clinical trials;
- delays in the importation and manufacture of clinical supply;
- delays in the testing, validation and delivery of the clinical supply of the product candidates to the clinical sites;
- for clinical trials in selected subject populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected subjects;
- delays in recruiting suitable subjects to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or disease progression;



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- delays in adding new investigators and clinical trial sites;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Any inability by us or our partners to timely complete clinical development could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales.

***If we are unable to enroll appropriate subjects in clinical trials, we will be unable to complete these trials on a timely basis or at all.***

Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit appropriate subjects to participate in testing our product candidates as well as completion of required follow-up periods. If subjects are unwilling to participate in our trials because of negative publicity from adverse events in the biotechnology industry or for other reasons, including competitive clinical trials for similar subject populations, the timeline for recruiting subjects, conducting trials and obtaining marketing approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. Many factors affect subject enrollment, including:

- the size and nature of the subject population;
- the number and location of clinical sites we enroll;
- the proximity of subjects to clinical sites;
- perceived risks and benefits of the product candidate under trial;
- competition with other companies for clinical sites or subjects;
- competing clinical trials;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- effectiveness of publicity for the clinical trials;
- inability to obtain and maintain subject consents;
- ability to monitor subjects adequately during and after the administration of the product candidate and the ability of subjects to comply with the clinical trial requirements;
- risk that enrolled subjects will drop out or be withdrawn before completion; and
- clinicians' and subjects' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

There is significant competition for recruiting subjects in clinical trials for product candidates for the treatment of depression, substance use disorders and impaired executive function, and we or our partners may be unable to enroll the subjects we need to complete clinical trials on a timely basis or at all. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited

influence over their actual performance. If we are unable to enroll sufficient subjects in our clinical trials, if enrollment is slower than we anticipate, or if our clinical trials require more subjects than we anticipate, our clinical trials may be delayed or may not be completed. If we experience delays in our clinical trials, the commercial prospects of our product candidates will be harmed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

***We may in the future conduct, clinical trials for certain of our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.***

We may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles and current Good Clinical Practice, or GCPs. The trial population must also adequately represent the United States population, and the data must be applicable to the United States population and United States medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable United States laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any of our clinical trials that we determine to conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the product candidate.

***We may fail to successfully identify, in-license, acquire, develop or commercialize potential product candidates.***

The success of our business depends in part upon our ability to identify and validate new therapeutic targets and identify, develop and commercialize therapeutics, which we may develop ourselves, in-license or acquire from others. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research efforts may initially show promise in identifying potential therapeutic targets or candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our methodology, including our screening technology, may not successfully identify medically relevant potential product candidates;
- our competitors may develop alternatives that render our product candidates obsolete;
- we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable;
- our product candidates may cause adverse effects in subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- our product candidates may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- our product candidates may not demonstrate a meaningful benefit to subjects;

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- our potential collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product; and
- our reliance on third party clinical trials may cause us to be denied access to clinical results that may be significant to further clinical development.

Additionally, we may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations.

***We may not be successful in our efforts to leverage and expand our COMTi platform to build a pipeline of product candidates.***

A key element of our strategy is to leverage and expand our COMTi platform to build a pipeline of product candidates for conditions with impairment of executive function, and to progress these product candidates through clinical development for the treatment of a variety of different types of diseases states involving impaired executive functioning. To date, we have selected a preclinical lead candidate for our COMTi platform, CERC-406, but CERC-406 or any other product candidates developed from our COMTi platform may not be safe or effective. Further, our continued development of the COMTi platform will be dependent upon receiving positive preclinical and clinical data that, in our judgment, merits advancing such program. Even if we are successful in continuing to build and expand our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

***The marketing approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, costly and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.***

The time required to obtain approval to market new drugs by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval. Moreover, the filing of an NDA requires a payment of a significant NDA user fee upon submission. The filing of an NDA for our product candidates may be delayed due to our lack of financial resources to pay such user fee.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree on the design or implementation of our clinical trials, including the methodology used in our studies, our chosen endpoints, our statistical analysis, or our proposed product indication. For instance, the FDA may find that the designs that we are utilizing in our completed and planned Phase 2 clinical trials of CERC-301 and CERC-501 do not support an adequate and well-controlled study. The FDA also may not agree with the various depression and other disease scales and evaluation

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tools that we are using in our clinical trials to assess the efficacy of our product candidates. Further, the FDA may not agree with our endpoints and/or indications selected for our studies for CERC-301 and CERC-501;

- the FDA or comparable foreign regulatory authorities may disagree with our development plans for our product candidates. For instance, at this time we have not yet discussed our development plans for either CERC-501 or CERC-406 with the FDA. While we plan to discuss the development of these product candidates with the FDA, the FDA may not agree with our current development approach;
- our failure to demonstrate to the satisfaction of the FDA or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
- our clinical trials may fail to meet the level of statistical significance required for approval. For example, in a proof of concept study of CERC-301 conducted by the National Institute of Mental Health, CERC-301 failed to provide a significant improvement in subjects receiving the compound as compared to those receiving a placebo, as measured by the Montgomery-Asberg Depression Rating Scale, the primary assessment tool. Significant improvements were, however, observed using alternative assessment tools, such as the Hamilton Depression Inventory 17 item scale or the Beck Depression Inventory. Further, our Clin301-201 Phase 2 study for CERC-301 failed to meet its primary endpoint;
- we may fail to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may be insufficient to support the submission and filing of an NDA, other submission or to obtain marketing approval. For example, the FDA may require additional studies to show that our product candidates are safe or effective;
- we may fail to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- there may be changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, including more limited patient populations, may require that contraindications, warnings or precautions be included in the product labeling, including a black-boxed warning, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-market requirements, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

***A fast track product, breakthrough therapy or priority review designation by the FDA for our product candidates may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.***

We have received a fast track product designation for CERC-301 for the treatment of MDD and we may seek a breakthrough therapy designation and priority review designation. For CERC-501, or for certain of our other product candidates, if supported by the results of clinical trials, we may seek fast track product designation, breakthrough therapy designation and priority review designation. A fast track product designation is designed to facilitate the clinical development and expedite the review of drugs intended to treat a serious or life-threatening condition which demonstrate the potential to address an unmet medical need. 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 significant endpoints, such as substantial treatment effects observed early in clinical development. Priority review designation is intended to speed the FDA marketing application review timeframe for drugs that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. For drugs and biologics that have been designated as fast track products or breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development. Sponsors of drugs designated as fast track products or breakthrough therapies may also be able to submit marketing applications on a rolling basis, meaning that the FDA may review portions of a marketing application before the sponsor submits the complete application to the FDA, as long as the sponsor pays the user fee upon submission of the first portion of the marketing application. For products that receive a priority review designation, the FDA's marketing application review goal is shortened to six months, as opposed to ten months under standard review. This review goal is based on the date the FDA accepts the marketing application for review, which typically adds approximately two months to the timeline for review and decision from the date of submission.

Designation as a fast track product, breakthrough therapy or priority review product is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a fast track product, breakthrough therapy or priority review product, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, with regard to fast track products and breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification as either a fast track product or a breakthrough therapy or, for priority review products, decide that the time period for FDA review or approval will not be shortened.

***As appropriate, we intend to seek all available periods of regulatory exclusivity for our product candidates. However, there is no guarantee that we will be granted these periods of regulatory exclusivity or that we will be able to maintain these periods of exclusivity.***

The FDA grants product sponsors certain periods of regulatory exclusivity, during which the agency may not approve, and in certain instances, may not accept, certain marketing applications for competing drugs. For example, product sponsors may be eligible for five years of exclusivity from the date of approval of a new chemical entity, seven years of exclusivity for drugs that are designated to be orphan drugs, and/or a six-month period of exclusivity added to any existing exclusivity period or patent life for the submission of FDA requested pediatric data. While we intend to apply for all periods of market exclusivity that we may be eligible for, there is no guarantee that we will receive all such periods of market exclusivity. Additionally, under certain circumstances, the FDA may revoke the period of market exclusivity. Thus, there is no guarantee that we will be able to maintain a period of

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market exclusivity, even if granted. Moreover, we have not sought to obtain orphan drug designation for any of our product candidates, which the FDA must first grant to be eligible for orphan drug exclusivity, but may if we determine that we may be eligible. In the case of orphan designation, other benefits, such as tax credits and exemption from user fees may be available. If we are not able to obtain or maintain orphan drug designation or any period of market exclusivity to which we may be entitled, we will be materially harmed, as we will potentially be subject to greater market competition and may lose the benefits associated with programs.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authority. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, our Phase 2 clinical trials for CERC-301 could reveal adverse events, including, but not limited to, dose-related increases in blood pressure, palpitations, sleepiness, forgetfulness, headache, dizziness, fatigue, lightheadedness or impaired concentration. In our completed Phase 2 clinical study, Clin301-201, in general, CERC-301 was well tolerated with rates of adverse events similar to that of placebo. The most common treatment emergent adverse events were nervous system disorders, occurring in 25.9% and 26.9%, respectively, of subjects in the two active treatment sequences compared to 22.4% of subjects who received placebo during the entire study. Of the nervous system treatment emergent adverse events, dizziness was most common, occurring in 18.5% and 7.7%, respectively, of subjects in the two active treatment sequences compared to 2.0% of subjects who received placebo during the entire study. Four serious adverse events in three subjects were reported during the conduct of the study, two in a subject randomized to placebo (suicide attempt; alcoholism) and two in subjects that received CERC-301 (worsening depression with psychotic features and unstable angina). Overall, the adverse events observed in this study were generally consistent with the prior clinical trials conducted for CERC-301. In our planned clinical study of CERC-301, CLIN301-203, we will be increasing the CERC-301 dose administered to subjects. This dose increase could increase the risk of serious adverse events. Also, based on the previous studies conducted for CERC-501, Phase 2 studies of CERC-501 could reveal adverse events, including, but not limited to, dizziness, nausea, diarrhea, headache, anxiety, tachycardia and dyspepsia.

Should our clinical studies of our product candidates reveal undesirable side effects, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities as well as IRBs could order us to suspend or cease clinical trials. The FDA or comparable regulatory authorities could also deny approval of our product candidates for any or all targeted indications or only for a limited indication or patient population or could require label warnings, contraindications or precautions, including black box warnings, post-market studies, testing and surveillance programs or other conditions including distribution restrictions or other risk management mechanisms under a risk evaluation and mitigation strategy, or REMS. Drug-related side effects could affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;

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- regulatory authorities may require additional warnings on the label or other label modifications;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a REMS or other restrictions on marketing and distribution, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such side effects for distribution to patients or restrict distribution of our products and impose burdensome implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

### ***Changes in product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates are developed through preclinical studies to late-stage clinical trials towards regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval.

Similarly, changes in the location of manufacturing or addition of manufacturing facilities may increase our costs, and require additional studies and FDA approval. This may require us to ensure that the new facility meets all applicable regulatory requirements, is adequately validated and qualified, and to conduct additional studies of product candidates manufactured at the new location. Any of the above could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay regulatory approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

### ***Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a more narrow indication than we expect.***

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain marketing approval from the relevant regulatory agencies. Additional delays may result if the FDA, an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for fewer or more limited indications than requested, may impose significant limitations in the form of narrow indications, warnings, including black-box warnings, precautions or contra-indications with respect to conditions of

use or may grant approval subject to the performance of costly post-marketing clinical trials or other post-marketing requirements, including a REMS. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. For instance, in 2007, the FDA requested that makers of all antidepressant medications update an existing black-box warning about an increased risk of suicidal thought and behavior. Our drugs, if approved, may be required to carry warnings comparable to this and other class-wide warnings. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

***Even if our product candidates receive marketing approval, we will still be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Even if we obtain marketing approval for a product candidate, we would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. In addition, any marketing approvals that we obtain for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and other requirements, including Phase 4 clinical trials, imposition of a REMS and surveillance to monitor the safety and efficacy of the product candidate. For example, during a meeting with the FDA regarding CERC-301, the FDA noted that it does not currently accept the explicit labeling claim of a rapid-acting antidepressant, or RAAD, and indicated that we may therefore be subject to limitations on our ability to label and promote the product as a RAAD upon approval.

In addition, manufacturers of drug products and their facilities, including contracted facilities, are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practice, or GMP, regulations and standards. If we or a regulatory agency discover 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, we may be subject to reporting obligations and a regulatory agency may impose restrictions on that product, the manufacturing facility or us, or our suppliers, including requesting recalls or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, our contractors, the manufacturing facilities for our product candidates or others working on our behalf fail to comply with applicable regulatory requirements, either before or after marketing approval, a regulatory agency may:

- issue Warning Letters or Untitled Letters;
- mandate modifications to promotional materials or labeling, or require us to provide corrective information to healthcare practitioners;



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- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines, restitution or disgorgement, as well as imprisonment;
- suspend or withdraw marketing approval;
- suspend or terminate any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- debar us from submitting marketing applications, exclude us from participation in federal healthcare programs, require a corporate integrity agreement or deferred prosecution agreements, debar us from government contracts and refuse future orders under existing contracts;
- suspend or impose restrictions on operations, including restrictions on marketing, distribution or manufacturing of the product, or the imposition of costly new manufacturing requirements or use of alternative suppliers; or
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. While the FDA does not restrict physicians from prescribing approved drugs for uses outside of the drugs' approved labeling, known as off-label use, pharmaceutical manufacturers are prohibited from promoting and marketing their products for such uses. Violations, including promotion of our products for off-label uses, are subject to enforcement letters, inquiries, investigations, civil and criminal sanctions by the government, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and refusal of future orders under existing contracts, and exclusion from participation in federal healthcare programs. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, debarment from government contracts and refusal of future orders under existing contracts, deferred prosecution agreements, and corporate integrity agreements with governmental authorities that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in any fines or settlement funds. If the government does not intervene, the individual may proceed on his or her own. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, such as settlements regarding certain sales practices promoting off-label drug uses involving fines that are as much as \$3.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to

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defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***If we are unable to, or are delayed in obtaining, state regulatory licenses for the distribution of our products, we would not be able to sell our product candidates in such states.***

The majority of states require manufacturer and/or wholesaler licenses for the sale and distribution of drugs into that state. The application process is complicated, time consuming and requires dedicated personnel or a third party to oversee and manage. If we are delayed in obtaining these state licenses, or denied the licenses, even with FDA approval, we would not be able to sell or ship product into that state which would adversely affect our sales and revenues.

***If any of our product candidates are ultimately regulated as controlled substances, we, our contract manufacturers, as well as distributors, prescribers, and dispensers will be required to comply with additional regulatory requirements which could delay the marketing of our product candidates, and increase the cost and burden of manufacturing, distributing, dispensing, and prescribing our product candidates.***

Before we can commercialize our product candidates, the United States Drug Enforcement Administration, or DEA, may need to determine the controlled substance Schedule, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. While we currently do not know whether any of our product candidates will be considered to be controlled substances, certain of our product candidates may be regulated as controlled substances.

If any of our product candidates are regulated as controlled substances, depending on the controlled substance schedule in which the product candidates are placed, we, our contract manufacturers, and any distributors, prescribers, and dispensers of the scheduled product candidates may be subject to significant regulatory requirements, such as registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. Moreover, if any of our product candidates are regulated as controlled substances, we and our contract manufacturers would be subject to initial and periodic DEA inspection. If we or our contract manufacturers are not able to obtain or maintain any necessary DEA registrations, we may not be able to commercialize any product candidates that are deemed to be controlled substances or we may need to find alternative contract manufacturers, which would take time and cause us to incur additional costs, delaying or limit our commercialization efforts.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates, should they be deemed to contain controlled substances. Failure to comply with the applicable controlled substance laws and regulations can also result in administrative, civil or criminal enforcement. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result

in criminal proceedings or consent decrees. Individual states also independently regulate controlled substances.

***Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States, which would limit our market opportunities and adversely affect our business.***

In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Also, regulatory approval for any of our product candidates may be withdrawn. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

***If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.***

If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for approval of drugs in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- 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;

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- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

***We face substantial competition and rapid technological change and the possibility that others may discover, develop or commercialize products before or more successfully than us.***

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain marketing approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

There are numerous currently approved therapies for treating depression and, consequently, competition in the depression market is intense. Many of these approved drugs are well established therapies or products and are widely accepted by physicians, patients and third party payors. Some of these drugs are branded and subject to patent protection and non patent regulatory exclusivity, and others are available on a generic basis. For example, CERC 301 will compete with drugs used as adjunctive therapies for the treatment of MDD such as Abilify, marketed by Otsuka America Pharmaceutical, Inc.; Seroquel XR, marketed by AstraZeneca Pharmaceuticals LP, or AstraZeneca; and bupropion, a generic drug. In addition, to our knowledge, there are five competitive rapid onset antidepressant or anti-suicide programs in development: esketamine, which is in Phase 3 development by Johnson & Johnson, or J&J, and is being developed to be administered as a nasal spray; AZD8108, which is in Phase 1 development by AstraZeneca and is being developed to be administered orally; Rapastinel, which is in Phase 3 development by Naurex Inc., or Naurex, which recently entered into an agreement to be acquired by Allergan plc., and is being developed to be administered intravenously; NRX 1074 by Naurex has completed a single intravenously administered dose Phase 2 study, which, along with oral and intravenous Phase 1 pharmacokinetic, or PK, findings, will be used to select an oral

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dose for a repeat-dose Phase 2 study; and ALKS-5461, which is in Phase 3 development by Alkermes plc, or Alkermes, and is being developed to be administered orally as an adjunctive therapy and has shown signals of rapid onset as an adjunctive therapy. With respect to CERC-501, to our knowledge, there are no approved pharmacologic treatments for co-occurring disorders, however, there are two competitive programs in development: ALKS 5461, which is believed to be acting as a functional KOR antagonist that is now in Phase 3 development for MDD as an adjunctive in patients who have no more than two inadequate responses to antidepressant therapy and LY2940094, which is in Phase 2 development by Eli Lilly and Company, or Lilly, and is being developed for the treatment of both MDD and alcohol dependence.

Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if CERC-301 is approved, it may be priced at a significant premium over competitive generic, including branded generic, products. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. This may make it difficult for us to differentiate our product from currently approved therapies, which may adversely impact our business strategy. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer. Moreover, many other companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- the claims we may make for our product candidates based on the approved label or any restrictions placed upon our marketing and distribution of our product candidates;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- how quickly and effectively we alone, or with a partner, can market and launch any of our product candidates that receive marketing approval;
- the ability to commercialize any of our product candidates that receive marketing approval;
- the price of our products, including in comparison to branded or generic competitors;
- the ability to collaborate with others in the development and commercialization of new products;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates;
- the entry of generic versions of our products onto the market;
- the number of products in the same therapeutic class as our product candidates;
- the ability to secure favorable managed care formulary positions, including federal healthcare program formularies;
- the ability to manufacture commercial quantities of any of our product candidates that receive marketing approval; and
- acceptance of any of our product candidates that receive marketing approval by physicians and other healthcare providers.

***Our product candidates may not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

Even if our product candidates receive marketing approval, they may not gain adequate market acceptance among physicians, patients and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, generally, which may be difficult or time-consuming to obtain, may be limited in scope or may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials;
- the claims we may make for our product candidates based on the approved label or any restrictions placed upon our marketing and distribution of our product candidates;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by physicians, providers and patients;
- the potential and perceived advantages of product candidates over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third parties and government authorities;
- relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, third-party payors and patients, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

***Even if we commercialize any of our product candidates, these products may become subject to unfavorable third-party coverage and reimbursement policies, healthcare reform initiatives, or pricing regulations, any of which could negatively impact our business.***

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products will be available from government authorities (such as Medicare and Medicaid), private health insurers, health maintenance organizations and other entities. These third-party payors determine which medications they will cover and establish reimbursement levels, and increasingly attempt to control costs by limiting coverage and the amount of reimbursement for particular medications. Several third-party payors are requiring that drug companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for drugs. In addition, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise

commercial prices. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates for a drug may vary according to the clinical setting in which it is used, and may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors, and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Moreover, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

***Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.***

We intend to in-license, acquire, develop and/or market additional neuropsychiatric products and product candidates, as well as other products and product candidates that address nervous system disorders. Because our internal research and development capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. In addition, companies that

perceive us to be a competitor may be unwilling to assign or license rights to us. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.***

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system and pharmaceutical industry that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for outpatient prescription drug purchases through pharmacies, by the elderly by establishing Medicare Part D and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that Medicare will cover in any therapeutic class under the new Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, the Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and other medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Therefore, any reduction in reimbursement that results from healthcare reform impacting government programs may result in a similar reduction in payments from private payors.



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In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act, a law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Among other things, the Affordable Care Act:

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, effective the first quarter of 2010;
- revised the definition of "average manufacturer price," or AMP, for reporting purposes, which can increase the amount of Medicaid drug rebates manufacturers are required to pay to states, and created a separate AMP for certain categories of drugs provided in non-retail outpatient settings;
- extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization;
- created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs;
- expanded the types of entities eligible to receive discounted 340B pricing, although, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above can cause the required 340B discounts to increase;
- imposed a significant annual fee on companies that manufacture or import branded prescription drug products;
- required manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole"; and
- enacted substantial new provisions affecting compliance which may affect our business practices with healthcare practitioners.

Although it is too early to determine the full effect of the Affordable Care Act, the new law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 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 to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013.

We expect that the Affordable Care Act, as well as other state and federal healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The

implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Moreover, the recently enacted Drug Quality and Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding drug products to individuals and entities to which product ownership is transferred, label drug products with a product identifier, and keep certain records regarding drug products. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products such that they would result in serious adverse health consequences or death, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our stock price.

We currently hold \$10.0 million in clinical trial liability insurance coverage, which may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain

marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

***Our relationships with commercial and government customers, healthcare providers, and third-party payors and others will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare related laws, regulations and requirements, which could expose us to criminal sanctions, civil penalties, exclusion from participation in federal healthcare programs, contractual damages and consequences, reputational harm, administrative burdens and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. There are also laws, regulations, and requirements applicable to the award and performance of federal grants and contracts. Actions resulting in violations of these laws regulations, and requirements may result in civil and criminal liability, damages and restitution, as well as exclusion from participation in federal healthcare programs, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts or contractual damages, and other consequences. Restrictions under applicable federal and state healthcare related laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the civil federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. Civil False Claims Act liability may be imposed for Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act;
- the criminal federal False Claims Act imposes criminal fines or imprisonment against individuals or entities who willfully make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the Veterans Health Care Act requires manufacturers of covered drugs to offer them for sale on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects us to contractual remedies as well as administrative, civil and criminal sanctions;

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- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal liability for, among other actions, knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- the civil monetary penalties statute imposes penalties against any person or entity who, among other things, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as directly applicable privacy and security standards and requirements;
- the federal Physician Sunshine Act, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members;
- the Foreign Corrupt Practices Act, or FCPA, prohibits any United States individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations; and
- analogous or similar state, federal, and foreign laws, regulations, and requirements such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign 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; state and foreign 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; laws, regulations, and requirements applicable to the award and performance of federal contracts and grants and state, federal and foreign laws that govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. For example, we must ensure that all applicable price concessions are included in prices calculated and reported to federal agencies. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and certain portions of the HIPAA criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Moreover, 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.

If our operations are found to be in violation of any of these laws or any other governmental regulations or requirements that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, restitution exclusion from government funded healthcare programs, such as Medicare and Medicaid, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts, contractual damages, the curtailment or restructuring of our operations and other consequences. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Moreover, availability of any federal grant funds which we may receive or for which we may apply is subject to federal appropriations law. Grant funding may also be withdrawn or denied for other reasons. For instance, the National Institutes of Mental Health, or NIMH, recently decided to discontinue the funding of a Phase 1 study of CERC-501 that was to be conducted by a third party as NIMH decided the study would be unlikely to provide new information beyond what a NIMH funded Phase 2a study, conducted by the same third party, would provide.

***If we fail to attract and keep management and other key personnel, as well as our board members, we may be unable to develop our product candidates or otherwise implement our business plan.***

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on Blake M. Paterson, M.D., our Chief Executive Officer and President and member of our board of directors. The loss of the services of Dr. Paterson could impede, delay or prevent the development of our product candidates and could negatively impact our ability to successfully implement our business plan. If we lose the services of Dr. Paterson, we may not be able to find a suitable replacement on a timely basis, or at all, and our business would likely be harmed as a result. We do not maintain a "key man" insurance policy on Dr. Paterson's life or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies.

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We may not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our 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. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

***If our employees, independent contractors, principal investigators, CROs, manufacturers, consultants or vendors commit fraud or other misconduct, including noncompliance with regulatory standards and requirements and insider trading, our business may experience serious adverse consequences.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, manufacturers, 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. The improper use of information obtained in the course of clinical trials could also result in significant legal sanctions and serious harm to our reputation. In addition, federal procurement laws and regulations impose substantial penalties for misconduct in connection with government contracts and require contractors to maintain a code of business conduct and ethics. In contemplation of this offering, we will adopt a Code of Business Conduct and Ethics, but 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 regulatory enforcement action, the imposition of significant criminal and civil fines, penalties, or other sanctions, including imprisonment, exclusion from participation in federal healthcare programs, and deferred prosecution and corporate integrity agreements.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. In contemplation of this offering, we will adopt an Insider Trading Policy, but despite the adoption of such policy, we may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material,

nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

***We may encounter difficulties in managing our growth and expanding our operations successfully.***

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, administrative, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. The hiring, training and integration of new employees may be more difficult, costly and/or time-consuming for us because we have fewer resources than a larger organization. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

***If, in the future, we are unable to establish our own sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in commercializing our product candidates.***

We currently have a relatively small number of employees and do not have a sales or marketing infrastructure, and we do not have any significant sales, marketing or distribution experience. We will be opportunistic in seeking to either build our own commercial infrastructure to commercialize our product candidates and future products if and when they are approved, or enter into licensing or collaboration agreements to assist in the future development and commercialization of such products.

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that our product candidates will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the clinical benefits of our products to achieve market acceptance;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the costs associated with training sales personnel on legal compliance matters and monitoring their actions;
- liability for sales personnel failing to comply with the applicable legal requirements; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Where and when appropriate, we may elect to utilize contract sales forces or strategic partners to assist in the commercialization of our product candidates. If we enter into arrangements with third

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parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. Such third parties may also not comply with the applicable regulatory requirements, which could potentially expose us to regulatory and legal enforcement actions.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

### **Risks Related to Our Dependence on Third Parties**

*We may not succeed in establishing and maintaining development collaborations, which could adversely affect our ability to develop and commercialize product candidates.*

A part of our strategy is to enter into product development collaborations in the future, including collaborations with major biotechnology or pharmaceutical companies for the development or commercialization of our current and future product candidates. We face significant competition in seeking appropriate development partners and the negotiation process is time-consuming and complex. We may not succeed in our efforts to establish development collaborations or other alternative arrangements for any of our existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy.

Furthermore, any collaborations that we enter into may not be successful. The success of our development collaborations will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a development collaboration regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the development collaboration. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Even if we are successful in our efforts to establish development collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into development collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market. Additionally, collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

If we fail to establish and maintain additional development collaborations related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;



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- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing, which may not be available on favorable terms, or at all;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates;
- we may have to expend unexpected efforts and funds if we are unable to obtain the results of third party clinical trials; and
- the competitiveness of any product candidate that is commercialized could be reduced.

***We rely on third parties to conduct, supervise and monitor our clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all.***

We rely upon third-party CROs to monitor and manage data for our clinical programs. We rely on these parties for execution of our clinical trials and, while we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our clinical trial sites, and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we, any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, 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, if at all. In addition, we are required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or 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 or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests, or significant payments of other sorts. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP requirements. In addition, we must conduct our clinical trials with product produced under applicable GMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the marketing approval process.

Our CROs and clinical trial sites are not our employees, and, except for remedies available to us under our agreements with such CROs and clinical trial sites, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. These CROs and clinical trial sites may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If CROs or clinical trial sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated

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and we may not be able to obtain marketing approval for or successfully commercialize our product candidates or we may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. 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, prospects, financial condition and results of operations.

***We use third parties to manufacture all of our product candidates. This may increase the risk that we will not have sufficient quantities of our product candidates to conduct our clinical trials or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates.***

We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale.

We currently outsource all manufacturing of our product candidates to third parties typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our product candidates may delay the development or commercialization of our other product candidates.

In addition, we do not currently have any agreements with third-party manufacturers for the long-term commercial supply of our product candidates. We may be unable to enter agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time.

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. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as GMP requirements, for manufacture of both active drug substances and finished drug products for clinical supply and eventually for commercial supply, if we receive regulatory approval. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. Failure of our contract manufacturers to comply with the applicable regulatory requirements may also subject us to regulatory enforcement actions. In addition, other than through our contractual agreements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

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Reliance on third-party manufacturers subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities; and
- the disruption and costs associated with changing suppliers, including additional regulatory filings.

Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under GMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control, manufacturing, and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions.

### **Risks Related to Intellectual Property**

***If we are unable to obtain or maintain intellectual property rights, or if the scope of patent protection is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and we may not be able to compete effectively in our market.***

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaborators. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree

with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

***If we breach the license agreements related to our product candidates, we could lose the ability to develop and commercialize our product candidates.***

Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to develop, manufacture, market and sell our product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates or face other penalties under these agreements. We have entered into exclusive license agreements with Merck & Co., Inc. and its affiliates, or Merck, pursuant to which Merck has granted us rights to the compounds used in CERC-301 and the COMTi platform, including CERC-406. We have also entered into exclusive license agreements with Lilly pursuant to which Lilly has granted us rights to the compounds used in CERC-501. If we fail to comply with the obligations under these agreements, including payment terms, Merck and Lilly may have the right to terminate any of these agreements, in which event we may not be able to develop, market or sell CERC-301, CERC-501 or any product candidate developed from the COMTi platform, including CERC-406. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Obtaining and maintaining our 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 and annuity fees on any issued patent are due to be paid to the United States Patent and Trademark Office, or USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, inter partes reviews or derivation proceedings before the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. 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 become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.***

Third parties may infringe our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the

validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors or collaborators may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' or collaborators' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Third party preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

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. There could also 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 material adverse effect on the price of shares of our common stock.

***We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In addition, we may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property

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to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement to each party who in fact develops intellectual property that we regard as our own. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

### ***Our inability to protect our confidential information and trade secrets would harm our business and competitive position.***

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Though we seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, as well as by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, 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.

### ***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' 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 United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and

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, only became effective on March 16, 2013. Accordingly, it is not 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 or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or collaborators may not be able to prevent third parties from practicing our and our licensors' or collaborators' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' or collaborators' 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 and our licensors or collaborators have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. 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 and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third



parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

### **Risks Related to this Offering and Ownership of Our Common Stock**

*We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.*

Prior to this offering, no market for shares of our common stock existed and an active trading market for our shares may never develop or be sustained following this offering. We will determine the initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price, or at all. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

*The market price of our stock may be volatile, and you could lose all or part of your investment.*

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price, or at all. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the development status of our product candidates, and when any of our product candidates receive marketing approval;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our failure to commercialize our product candidates, if approved;
- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;

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- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- the performance of third parties on whom we rely to manufacture our products and product candidates, supply API and conduct our clinical trials, including their ability to comply with regulatory requirements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- variations in the level of expenses related to our product candidates or preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions in the pharmaceutical and biotechnology sectors;
- our execution of collaborative, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the Securities and Exchange Commission, or SEC, and announcements relating to litigation or other disputes, strategic transactions or intellectual property impacting us or our business;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- ratings downgrades by any securities analysts who follow our common stock;
- the development and sustainability of an active trading market for our common stock;
- future sales of our common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;

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- changes in accounting principles; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

***We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.***

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We may take advantage of these exemptions until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" upon the earliest of: (i) the first fiscal year following the fifth anniversary of this offering; (ii) the first fiscal year after our annual gross revenues are \$1 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700 million as of the end of the second quarter of that fiscal year.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company." For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting

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go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC which may make it more difficult for investors and securities analysts to evaluate our company. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. 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 and may decline.

***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.***

Upon closing of this offering, our executive officers, directors and 5% stockholders and their affiliates will beneficially own approximately 8.8% of our outstanding voting stock. As a result, these stockholders will have significant influence and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership could delay or prevent any acquisition of our company on terms that other stockholders may desire.

***We have broad discretion in the use of the net proceeds from this offering and may not apply the proceeds in ways that increase the value of your investment.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will be relying on the judgment of our management regarding the application of these proceeds. We intend to use the net proceeds from this offering for:

- Phase 2 clinical development of CERC-301 and CERC-501;
- research and development under our COMTi platform, including the selection of lead candidates and preclinical research for CERC-406; and
- working capital and other general corporate purposes.

In addition, a portion of the net proceeds may also be used to acquire or license products, technologies or businesses. However, we do not currently have any specific plans for use of the net proceeds from this offering, nor have we performed studies or made preliminary decisions with respect to the best use of the capital resources resulting from this offering. As such, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock. You will be relying on the judgment of our management concerning these uses and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The failure of our management to apply these funds effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. Any adverse determination in litigation could also subject us to significant liabilities.

***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. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

***Future sales of our common stock may depress our stock price.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding 8,860,912 shares of common stock based on the number of shares outstanding as of June 30, 2015, assuming (i) no exercise of the underwriters' over-allotment option; and (ii) the conversion of all outstanding shares of our convertible preferred stock into 3,980,422 shares of common stock immediately prior to the closing of this offering. 4,230,769 shares will be eligible for resale on the public market immediately, and 4,630,143 of the shares may be sold after the expiration of lock-up agreements or other similar contractual commitments restricting the sale of such shares at least 180 days after the date of this prospectus pursuant to Rule 144 or Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, unless held by an affiliate of ours, as more fully described in the section entitled "Shares Eligible for Future Sale."

We also intend to register all shares of common stock that we may issue after this offering under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described above and in the section entitled "Underwriting—Lock-Up Agreements."

If a large number of shares of our common stock or securities convertible into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

***We will incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC, the NASDAQ Capital Market and other applicable securities

rules and regulations imposed on public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. The impact of these requirements 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.

We estimate the additional annual cost that we will incur as a result of our public company reporting obligations is \$2.0 million. However, because these rules and regulations are often subject to varying interpretations, it is difficult to accurately estimate or predict the amount or timing of these additional costs. Further, the lack of specificity of many of the rules and regulations may result in an application in practice that may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

***If you purchase shares of common stock sold in this offering, you will incur immediate and substantial dilution.***

If you purchase shares of common stock in this offering, you will incur immediate and substantial dilution in the pro forma as adjusted amount of \$4.20 per share, assuming an initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, because you will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. Moreover, investors who purchase shares of common stock in this offering will contribute approximately 35% of our total funding to date but will own only approximately 48% of our outstanding shares after giving effect to this offering. In addition, you may also experience additional dilution if the underwriters exercise their over-allotment option, upon future equity issuances, including upon conversion of any outstanding debt, or the exercise of stock options to purchase common stock granted to our employees, consultants and directors under our stock option and equity incentive plans. Please see the section entitled "Dilution."

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

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

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

Upon the closing 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

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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 error or mistake. 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.

***Our amended and restated certificate of incorporation that will become effective upon the Closing of this offering will provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation that will become effective upon the Closing of this offering will provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the company; (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the company to the company or the company's stockholders; (iii) any action asserting a claim against the company arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, each of which will become effective upon the closing of this offering; or (iv) any action asserting a claim against the company governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the closing of this offering, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- providing for a classified board of directors, with each director serving a staggered three-year term;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and

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- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

The continued operation and expansion of our business will require substantial funding. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, if you purchase shares in this offering, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.



## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that reflect our management's beliefs and views with respect to future events and are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" or the negative of those terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- our estimates regarding our expenses, future revenues, anticipated capital requirements and our needs for additional financing;
- our ability to advance our product candidates into, and successfully complete, clinical trials and the anticipated timing of such clinical trials;
- the timing of and our ability to obtain and maintain marketing approvals for our product candidates and the anticipated regulatory pathways for our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- the size and potential growth of the markets for any of our product candidates and our ability to impact the size of those markets;
- our expectations regarding the potential safety, efficacy or clinical utility of our product candidates, particularly in comparison to our competitors' products and product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the timing of the initiation, progress and results of preclinical studies and research and development programs;
- market and industry trends;
- our ability to leverage the experience of our management team;
- our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;
- our intellectual property position;
- our ability to identify additional products or product candidates, including from our COMTi platform, with significant commercial potential that are consistent with our commercial objectives; and
- our anticipated use of the net proceeds from this offering.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. We operate in a very competitive and rapidly changing environment. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and accordingly you should not place undue reliance on our forward-looking statements. We have included important factors in the cautionary statements included in this prospectus, particularly in

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the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

## USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 4,230,769 shares of our common stock in this offering will be approximately \$22.7 million, assuming an initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds from this offering will be approximately \$26.5 million, assuming an initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase or decrease in the assumed initial public offering price of \$6.50 per share would increase or decrease the net proceeds from this offering by approximately \$3.9 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Similarly, a one million share increase or decrease in the number of shares offered by us would increase or decrease the net proceeds to us by \$5.9 million, assuming the initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. As of June 30, 2015, we had cash and cash equivalents of \$6.1 million. We plan to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$9.0 million to fund the costs of our Phase 2 clinical development of CERC-301;
- approximately \$7.0 million to fund the costs of our Phase 2 clinical development of CERC-501;
- approximately \$1.5 million to fund research and development, and to advance our pipeline of preclinical lead candidates, under the COMTi platform, including the selection of additional candidates and preclinical research for CERC-406; and
- the remainder for working capital, general corporate purposes and potential in-licensing or other acquisitions.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials for CERC-301 and CERC-501, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We have no current understandings, agreements, commitments or obligations to in-license, acquire or invest in complementary businesses, technologies, products or assets.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to complete Phase 2 clinical development of CERC-301 and CERC-501, preclinical research for CERC-406, and identify other preclinical lead candidates from our COMTi platform. It is possible that we will not achieve the progress that we expect with respect to CERC-301 and our COMTi platform because the

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actual costs and timing of development and marketing approval are difficult to predict and are subject to substantial risks and delays.

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

## **DIVIDEND POLICY**

We have never declared or paid cash dividends on our capital stock. We intend to retain all of our available funds and future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2015:

- on an actual basis;
- on a pro forma basis to give effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,980,422 shares of our common stock upon the closing of this offering and (ii) the reclassification of approximately \$1.5 million related to the investor rights obligation and warrant liability from liabilities to permanent equity upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 4,230,769 shares of our common stock in this offering at an assumed initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The information in this table is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table in conjunction with the information contained in the "Management's Discussion and Analysis of Financial Condition and Results of

Operations" section of this prospectus and with our financial statements and the notes thereto included elsewhere in this prospectus.

	As of June 30, 2015		
	Actual	Pro forma (in thousands)	Pro forma as adjusted
Cash and cash equivalents	\$ 6,143	\$ 6,143	\$ 28,854
Liabilities:			
Term debt (net of debt discount)	\$ 7,053	\$ 7,053	\$ 7,053
Convertible Preferred Stock:			
Series A convertible preferred stock, \$0.001 par value; 31,116,391 shares authorized, 31,116,391 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	10,463	—	—
Series A-1 convertible preferred stock, \$0.001 par value; 9,074,511 shares authorized, 9,074,511 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	3,389	—	—
Series B convertible preferred stock, \$0.001 par value; 115,000,000 shares authorized, 58,948,735 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	14,493	—	—
Total convertible preferred stock	28,345	—	—
Stockholders' (deficit) equity:			
Common stock, \$0.001 par value; 230,000,000 shares authorized and 649,721 shares issued and outstanding, actual; 230,000,000 shares authorized and 4,630,143 shares issued and outstanding, pro forma; 200,000,000 shares authorized and 8,860,912 shares issued and outstanding, pro forma as adjusted	1	5	9
Preferred stock, par value \$0.001; no shares authorized, issued and outstanding, actual and pro forma; 5,000,000 shares authorized, no shares issued and outstanding, pro forma as adjusted	—	—	—
Additional paid in capital	17,034	46,895	69,602
Accumulated deficit	(49,224)	(49,224)	(49,224)
Total stockholders' (deficit) equity	(32,189)	(2,324)	20,387
Total capitalization	\$ 3,209	\$ 4,729	\$ 27,440

A \$1.00 increase or decrease in the assumed initial public offering price of \$6.50 per share would increase (decrease) each of the pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately \$3.9 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately \$5.9 million, assuming that the assumed initial public offering price, which is the midpoint of the price range set forth on the cover

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page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above does not include:

- 510,884 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2015 at a weighted-average exercise price of \$8.88 per share;
- 490,756 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2015 at a weighted-average exercise price of \$26.32 per share, which warrants are expected to remain outstanding upon the closing of this offering;
- 166,718 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2015 at a weighted-average exercise price of \$8.40 per share, which warrants will expire upon the closing of this offering in accordance with their terms, unless exercised prior thereto;
- 22,328 shares of our common stock issuable upon the exercise of a warrant outstanding as of June 30, 2015 at an exercise price of \$8.40 per share, which warrant is exercisable to purchase Series B convertible preferred stock prior to the completion of this offering and which warrant is expected to remain outstanding upon the closing of this offering;
- 42,307 shares of our common stock issuable upon the exercise of the warrants issued in connection with this offering to the Underwriters at an exercise price of \$7.48, assuming an initial public offering price of \$6.50 per share, which is the midpoint of this price range set forth on the cover page of this prospectus and a total of 4,230,769 shares of our common stock are sold in this offering;
- 254,236 shares of our common stock available for future issuance under our 2011 Stock Incentive Plan as of June 30, 2015, which upon effectiveness of our 2015 Omnibus Incentive Compensation Plan will be available for issuance under our 2015 Omnibus Incentive Compensation Plan; and
- 890,815 shares of our common stock available for future issuance under our 2015 Omnibus Incentive Compensation Plan, which will become effective on the business day immediately preceding the date on which the registration statement is declared effective.



## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering. Net tangible book value per share of our common stock is determined at any date by subtracting our total liabilities from the amount of our total tangible assets (total assets less intangible assets) and dividing the difference by the number of shares of our common stock deemed outstanding at that date.

The historical net tangible book value of our common stock as of June 30, 2015 was \$(3.8) million, or \$(5.92) per share of our common stock, based on 649,721 shares of our common stock outstanding as of June 30, 2015.

The pro forma net tangible book value of our common stock as of June 30, 2015 was \$(2.3) million, or \$(0.50) per share of our common stock, and represents our historical net tangible book deficit as of June 30, 2015 after giving effect to the conversion of all of our outstanding convertible preferred stock into an aggregate of 3,980,422 shares of our common stock.

After giving further effect to the sale of 4,230,769 shares of common stock by us in this offering at an assumed initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us our pro forma as adjusted net tangible book value as of June 30, 2015 would have been \$20.4 million, or \$2.30 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$2.80 per share to existing stockholders, and an immediate dilution of \$4.20 per share to investors participating in this offering. The table below illustrates this per share dilution.

Investors participating in this offering will incur immediate and substantial dilution. After giving further effect to our issuance and sale of 4,230,769 shares of our common stock in this offering at an assumed initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2015 would have been \$20.4 million, or \$2.30 per share. This represents an immediate increase in pro forma adjusted net tangible book value of \$2.80 per share to existing stockholders and immediate dilution of \$4.20 per share to new investors purchasing common stock in this offering. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$ 6.50
Historical net tangible book value per share as of June 30, 2015	(5.92)
Pro forma increase in net tangible book value (deficit) per share attributable the conversion of outstanding convertible preferred stock	<u>5.42</u>
Pro forma net tangible book value (deficit) per share before this offering	(0.50)
Pro forma increase in net tangible book value (deficit) per share attributable to new investors purchasing common stock in this offering	2.80
Pro forma as adjusted net tangible book value (deficit) per share after this offering	<u>2.30</u>
Dilution per share to new investors purchasing common stock in this offering	<u>\$ 4.20</u>

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A \$1.00 increase or decrease in the assumed initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value by \$3.9 million or by \$0.43 per share and the dilution to new investors in this offering by \$3.76 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We may also increase or decrease the number of shares we are offering. An increase of 1.0 million shares in the number of shares offered by us would increase our pro forma as adjusted net tangible book value (deficit) as of June 30, 2015, by approximately \$5.9 million or by \$0.37 per share and the dilution per share to new investors purchasing common stock in this offering by \$3.83, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Conversely, a decrease of 1.0 million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value (deficit) as of June 30, 2015, by approximately \$5.9 million or by \$0.46 per share and the dilution per share to new investors purchasing common stock in this offering by \$4.66, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value (deficit) per share after giving effect to this offering would be \$2.54 per share, which amount represents an immediate increase in pro forma net tangible book value (deficit) of \$0.24 per share of our common stock to existing stockholders and an immediate dilution in net tangible book value (deficit) of \$3.96 per share of our common stock to new investors purchasing shares of common stock in this offering.

The following table summarizes, as of June 30, 2015, on a pro forma basis after giving effect to the conversion of outstanding convertible preferred stock, the differences between the number of shares purchased from us, the total consideration paid to us, and the average price per share paid to us by existing stockholders and by new investors purchasing shares in this offering at an assumed initial public offering price of \$6.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price
	Number	Percentage	Amount	Percentage	Per Share
Existing shareholders	4,630,143	52%	\$ 51,100,000	65%	\$ 11.04
New investors	4,230,769	48%	27,499,999	35%	6.50
Total	8,860,912	100%	\$ 78,599,999	100%	\$ 8.87

The number of shares of our common stock outstanding immediately following this offering is based on 649,721 shares of our common stock outstanding as of June 30, 2015 and giving effect to the pro forma conversion of our convertible preferred stock into an aggregate of 3,980,422 shares of our common stock upon the closing of this offering. This number excludes:

- 510,884 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2015 at a weighted-average exercise price of \$8.88 per share;
- 490,756 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2015 at a weighted-average exercise price of \$26.32 per share, which warrants are expected to remain outstanding upon the closing of this offering;

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- 166,718 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2015 at a weighted-average exercise price of \$8.40 per share, which warrants will expire upon the closing of this offering in accordance with their terms, unless exercised prior thereto;
- 22,328 shares of common stock issuable upon the exercise of a warrant outstanding as of June 30, 2015 at an exercise price of \$8.40 per share, which warrant is exercisable to purchase Series B convertible preferred stock prior to the completion of this offering and which warrant is expected to remain outstanding upon the closing of this offering;
- 42,307 shares of our common stock issuable upon the exercise of the warrants issued in connection with this offering to the Underwriters at an exercise price of \$7.48, assuming an initial public offering price of \$6.50 per share, which is the midpoint of this price range set forth on the cover page of this prospectus and a total of 4,230,769 shares of our common stock are sold in this offering;
- 254,236 shares of our common stock available for future issuance under our 2011 Stock Incentive Plan as of June 30, 2015, which upon effectiveness of our 2015 Omnibus Incentive Compensation Plan will be available for issuance under our 2015 Omnibus Incentive Compensation Plan; and
- 890,815 shares of our common stock available for future issuance under our 2015 Omnibus Incentive Compensation Plan, which will become effective business day immediately preceding the date on which the registration statement is declared effective.

To the extent that outstanding stock options are subsequently exercised, there will be further dilution to new investors. If all outstanding options as of June 30, 2015 had been exercised, assuming the treasury stock method, the pro forma net tangible book value per share as of June 30, 2015 (calculated on the basis of the assumptions set forth above) would have been approximately \$(2.3) million, or \$(0.49) per share of our common stock, and the pro forma as adjusted net tangible book value would have been \$2.26 per share, representing dilution in our pro forma adjusted net tangible book value per share to new investors of \$0.04.

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 additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

Effective upon the closing of this offering, an aggregate of 1,145,051 shares of our common stock will be reserved for future issuance under our equity benefit plans, and the number of reserved shares will also be subject to automatic annual increases in accordance with the terms of the plans. New options that we may grant under our equity benefit plans will further dilute investors purchasing common stock in this offering.

If the underwriters exercise their over-allotment option in full, the following will occur:

- the percentage of shares of our common stock held by existing stockholders will decrease to approximately 49% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares of our common stock held by new investors will increase to approximately 51% of the total number of shares of our common stock outstanding after this offering.

## SELECTED FINANCIAL DATA

The following tables set forth our summary financial data for the periods indicated. The following summary financial data as of and for the years ended December 31, 2013 and 2014 are derived from our audited financial statements appearing elsewhere in this prospectus. The following summary financial data for the six-month periods ended June 30, 2014 and 2015, and the selected balance sheet data as of June 30, 2015, are derived from our unaudited financial statements appearing elsewhere in this prospectus.

This summary financial data should be read together with the historical financial statements and related notes to those statements, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations," which are included elsewhere in this prospectus. See note 3 to our audited financial statements appearing elsewhere in this prospectus for information regarding computation of basic and diluted net loss per share of common stock, unaudited pro forma basic and diluted net loss per share of common stock and the unaudited pro forma weighted average basic and diluted common shares outstanding used in computing pro forma basic and diluted net loss per common share.

	Years Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
<b>Operating expenses:</b>				
Research and development	\$ 8,914,084	\$ 12,240,535	\$ 5,610,764	\$ 3,598,606
General and administrative	4,020,364	4,875,030	1,673,573	1,776,817
Total operating expenses	<u>12,934,448</u>	<u>17,115,565</u>	<u>7,284,337</u>	<u>5,375,423</u>
Loss from operations	<u>(12,934,448)</u>	<u>(17,115,565)</u>	<u>(7,284,337)</u>	<u>(5,375,423)</u>
<b>Other income (expense):</b>				
Change in fair value of warrant liabilities and investor rights obligation	(121,115)	2,266,161	385,990	(337,739)
Interest income (expense), net	10,555	(1,206,187)	(794,038)	(437,302)
Total other income (expense):	<u>(110,560)</u>	<u>1,059,974</u>	<u>(408,048)</u>	<u>(775,041)</u>
Net loss	<u>\$ (13,045,008)</u>	<u>\$ (16,055,591)</u>	<u>\$ (7,692,385)</u>	<u>\$ (6,150,464)</u>
Net loss attributable to common stockholders	<u>\$ (13,126,972)</u>	<u>\$ (3,521,153)</u>	<u>\$ (7,692,385)</u>	<u>\$ (6,150,464)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (20.72)</u>	<u>\$ (5.48)</u>	<u>\$ (12.10)</u>	<u>\$ (9.47)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>633,669</u>	<u>642,052</u>	<u>635,714</u>	<u>649,721</u>
Pro forma net loss per share of common stock—basic and diluted (unaudited)		<u>\$ (1.01)</u>		<u>\$ (1.33)</u>
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)		<u>3,501,768</u>		<u>4,630,143</u>

	As of December 31,		As of June 30,
	2013	2014	2015
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 3,421,480	\$ 11,742,349	\$ 6,142,864
Total assets	5,075,600	12,316,894	7,582,120
Long term debt, net of current portion and discount	—	5,308,211	4,009,435
Total liabilities	3,065,642	10,302,027	11,425,504
Convertible preferred stock	19,856,633	28,345,531	28,345,531
Total stockholders' deficit	<u>(17,846,675)</u>	<u>(26,330,664)</u>	<u>(32,188,915)</u>

## 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 our financial statements and related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward looking statements that involve risks, uncertainties and assumptions. 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 this prospectus.*

### Overview

We are a clinical stage biopharmaceutical company with the goal of becoming a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. We have a portfolio of clinical and preclinical compounds that we believe are best in class and where human proof of concept has been established for the compound or the target. We are currently pursuing regulatory approval of three product candidates: CERC-301, CERC-501 and CERC-406.

CERC-301 is currently in Phase 2 development as an oral, adjunctive treatment of patients with major depressive disorder, or MDD, who are failing to achieve an adequate response to their current antidepressant treatment and are severely depressed. We received fast track designation by the United States Food and Drug Administration, or FDA, in November 2013 for CERC-301 for the treatment of MDD. CERC-301 belongs to a class of compounds known as antagonists, or inhibitors, of the N-methyl-D-aspartate, or NMDA, receptor, a receptor subtype of the glutamate neurotransmitter system that is responsible for controlling neurological adaptation. We believe CERC-301 will be a first-in-class medication that will cause a significant reduction in depression symptoms in a matter of days, as compared to weeks or months with conventional therapies, because it selectively blocks the NMDA receptor subunit 2B, or NR2B, which we believe provides rapid and significant antidepressant activity without the adverse side effect profile of non selective NMDA receptor antagonists. We are also currently developing CERC-501, which is in Phase 2 development. We intend to first develop CERC-501 for treatment of substance use disorders (e.g. nicotine, alcohol, and/or cocaine) and adjunctive treatment of MDD. If we receive approval for CERC-501 for treatment of substance use disorders and for adjunctive treatment of MDD, we plan to further develop CERC-501 for the concurrent treatment of MDD and substance use disorders, or co-occurring disorders. CERC-501 was acquired in February 2015, and is a potent and selective kappa opioid receptor, or KOR, antagonist. KORs are believed to play key roles in modulating stress, mood and addictive behaviors, which form the basis of co-occurring disorders. We are preparing to initiate a clinical study to evaluate the effect of CERC-501 on aspects of tobacco withdrawal and reinstatement in the first half of 2016. In addition we are considering conducting a Phase 2 clinical study in inadequately treated subjects with major depressive disorder currently on antidepressants, with an initiation date in the second half of 2016, with the intent of thereafter pursuing additional studies focused on the treatment of major depressive disorder, substance use disorders, and, depending on market approval, the treatment of co-occurring disorders. CERC-406 is our preclinical lead candidate from our proprietary platform of compounds that inhibit catechol-O-methyltransferase, or COMT, within the brain, which we refer to as our COMTi platform. We anticipate developing CERC-406 for the treatment of residual cognitive impairment symptoms in patients with MDD.

We incorporated in January 2011 and commenced operations in the second quarter of 2011. Since inception, our operations have included organizing and staffing our company, business planning, raising capital and developing our product candidates, CERC-301, CERC-501 and FP01, which we have

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discontinued developing, and the COMTi platform, including our initial product candidate CERC-406. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. We have incurred losses in each period since our inception. We have financed our operations primarily through private placements of our common and convertible preferred stock and convertible debt. As of June 30, 2015, we had an accumulated deficit of \$49.2 million. Our net loss was \$13.0 and \$16.1 million for the year ended December 31, 2013 and 2014, respectively, and \$6.2 million for the six months ended June 30, 2015. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate any product revenue unless, and until, we obtain marketing approval for, and commercialize, any of our product candidates.

We have received aggregate net proceeds of \$51.1 million through June 30, 2015 from the sale of our common and convertible preferred stock and convertible debt. In addition, we received \$292,000 pursuant to a grant agreement with the National Heart, Lung, and Blood Institute of the National Institute of Health, or NIH. From inception through June 30, 2015, we had incurred approximately \$36.0 million of total research and development expenses and approximately \$13.6 million of total general and administrative expenses.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek marketing approval for, our product candidates. If we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and outsourced manufacturing, unless we offset our commercialization expenses by entering into a favorable partnering arrangement with a third party. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our ability to achieve profitability is dependent on our ability, alone or with others, to (i) complete the development of our product candidates successfully, (ii) obtain required marketing approvals, (iii) manufacture and market our potential products successfully or have such products manufactured and marketed by others, and (iv) gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. We will seek to fund our operations through the sale of equity, debt financings or other sources, including potential collaborations. However, we may be unable to raise additional funds or enter into such other agreements when needed on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates.

Our recurring losses and negative cash flows from operations 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 regarding this uncertainty in its report on our financial statements as of and for the year ended December 31, 2014. We have no current source of revenues to sustain our present activities, and we do not expect to generate revenues until, and unless, the FDA or other regulatory agencies approve our product candidates and we successfully commercialize any such product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations.

## Components of Operating Results

### *Revenue*

To date, we have derived all of our revenue from a research grant from NIH, which we received in 2011. We do not expect any grant revenue during 2015 and, although we plan to submit grant applications from time to time, no assurances can be made that the grant will be awarded.

We have not generated any revenue from commercial product sales. In the future, if any of our product candidates currently under development are approved for commercial sale, we may generate revenue from product sales, or alternatively, we may choose to select a collaborator to commercialize our product candidates in all or selected markets, thereby reducing revenue from product sales or increasing fees paid to collaborators. We will not generate any commercial revenue, if ever, until one of our product candidates receives marketing approval and we successfully commercialize such product candidates.

### *Research and Development Expenses*

Our research and development expenses consist primarily of costs incurred developing, testing and seeking marketing approval for our product candidates. These costs include both external costs, which are study-specific costs, and internal research and development costs, which are not directly allocated to our product candidates.

External costs include:

- expenses incurred under agreements with third-party contract research organizations, or CROs, and investigative sites that conduct our clinical trials, preclinical studies and regulatory activities;
- payments made to contract manufacturers for drug substance and acquiring, developing and manufacturing clinical trial materials; and
- payments related to acquisitions of our product candidates and preclinical platform and milestone payments.

Internal costs include:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense;
- consulting costs related to our internal research and development programs;
- allocated facilities, depreciation and other expenses, which include rent and utilities, as well as other supplies; and
- product liability insurance.

Research and development costs are expensed as incurred. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our vendors.

We track external costs by discovery program and subsequently by product candidate once a product candidate has been selected for development. We have incurred a total of \$36.0 million in research and development expenses from inception through June 30, 2015, with \$13.0 million being spent on external costs primarily for CERC-301, \$1.1 million spent on CERC-501, \$11.2 million for our discontinued product candidate FP01, and \$1.3 million spent on our COMTi platform and other preclinical programs; the remaining \$9.5 million was spent primarily on internal costs, which are predominantly personnel-related costs, including stock-based compensation, and consulting and other costs. Product candidates in later stage clinical development generally have higher research and

development expenses than those in earlier stages of development, primarily due to the increased size and duration of the clinical trials. As we advance our product candidates through clinical development, we expect that the amount of our research and development spending allocated to external spending relative to internal spending will continue to grow for the foreseeable future, while our internal research and development spending should grow at a slower and more controlled pace.

During December 2014 and the first quarter of 2015, our research and development headcount was reduced by seven employees due to voluntary terminations. We expect to hire and to use consultants on an as needed basis to perform the work needed as we commence additional trials for CERC-301 and our first trial for CERC-501 during the second and third quarters of 2015. However, we anticipate that our research and development expenses for 2015 will be less than 2014. We anticipate that our research and development costs will increase in 2016 and beyond, with continued research, development and potential commercialization of our product candidates.

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, whether the trial results will be positive, or if, when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain marketing approval. We may never succeed in achieving marketing approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate, the number of clinical sites included in trials, and the need to add more sites, and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability, market acceptance and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential. A change in the outcome of any of the variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, based on the results of our Phase 2 clinical trials of FP01, expected future development expenses and the addressable market, we have decided to discontinue the development and commercialization of FP01. Additionally, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those which we anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

#### ***General and Administrative Expenses***

General and administrative expenses consist principally of professional fees, patent costs and salaries, benefits and related costs for executive and other personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, communication expenses and professional fees for legal, including patent-related expenses, consulting, tax and accounting services, insurance, depreciation and general corporate expenses.

We anticipate that our general and administrative expenses will increase in the future with continued research, development and potential commercialization of our existing and future product candidates and expanded compliance obligations of operating as a public company. These increases will likely include greater costs for insurance, costs related to the hiring of additional personnel, payments to outside consultants and investor relations providers, and costs for legal and accounting professionals, among other expenses. Additionally, if and when we believe a marketing approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.



### ***Change in Fair Value of Warrant Liabilities and Investor Rights Obligation***

We have issued warrants for the purchase of our Series B preferred stock and accounted for the obligation to issue additional shares of our Series B preferred as a freestanding financial instrument, which we refer to as the Investor Rights Obligation. The warrants and Investor Rights Obligation are classified as liabilities at their respective fair values. These liabilities are remeasured at each balance sheet date and changes in fair value are recorded within our statement of operations. We will remeasure the warrant liability immediately prior to the closing of this offering and, upon the conversion of such warrant into a warrant to purchase shares of our common stock upon the completion of this offering, we will reclassify these liabilities to permanent equity. The Investor Rights Obligation will expire upon the closing of this offering in accordance with its terms, unless exercised prior thereto.

### ***Interest Income (Expense), net***

Interest income (expense), is primarily related to the amortization of the debt discounts and premiums and deferred financing fees in connection with the entry into our term debt facility in August 2014. We also made interest payments pursuant to the terms of such term debt facility.

Interest income consists principally of interest earned on our cash and cash equivalent balances.

### ***Critical Accounting Policies and Significant Judgments and Estimates***

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. On an ongoing basis, we evaluate our estimates and assumptions, including those related to clinical and preclinical trial expenses and stock-based compensation. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our audited financial statements appearing at the end of this prospectus, we believe the following accounting policies are critical to the portrayal of our financial condition and results. We have reviewed these critical accounting policies and estimates with the audit committee of our board of directors.

#### ***Research and Development Expenses***

Research and development costs are expensed as incurred. We rely heavily on third parties to conduct preclinical and clinical trials, as well as for the manufacture of our clinical trial supplies. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

#### ***Income Taxes***

As of December 31, 2014, we had \$40.9 million of Federal and Maryland net operating loss, or NOL, carryforwards that will begin to expire in 2031. As of December 31, 2014, we had \$1.1 million

and \$0.5 million of Maryland and federal research and development credits, respectively, that will begin to expire in 2018. The NOL and research and development credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three- year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs that we can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. All of our tax years are currently open to examination by each tax jurisdiction in which we are subject to taxation.

#### *Convertible Preferred Stock*

We account for conversion options embedded in our convertible preferred stock in accordance with ASC 480, "*Distinguishing Liabilities from Equity*", ASC 815, "*Derivatives and Hedging*", and ASU 2014-16, an update to ASC 815. GAAP potentially requires companies to bifurcate conversion options from their host instruments and account for them as freestanding derivative financial instruments at their fair value according to certain criteria. The criteria includes circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable GAAP with changes in fair value reported in earnings as they occur, and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. We evaluated the Series A, A-1 and B convertible preferred stock and their embedded conversion features on the date of issuance and determined the host instruments and the embedded conversion features are more akin to equity and are therefore clearly and closely related as defined by ASC 815. As such, bifurcation of the embedded conversion feature was not required.

#### *Estimated Fair Value of Investor Rights Obligation*

On July 11, 2014 and August 19, 2014, we issued Series B convertible preferred stock for aggregate proceeds of \$15 million. In addition, we issued Series B convertible preferred stock upon conversion of our demand notes that had a an aggregate principal balance of \$1 million at the time of conversion, as well as the conversion of our convertible promissory notes that had an aggregate principal balance of \$1,250,000 and accrued interest of \$9,016. At any time after the initial offering and prior to the earlier of (i) an initial public offering, or IPO, (ii) a deemed liquidation event, or (iii) June 30, 2017, the majority holders of the Series B convertible preferred stock issued may purchase up to an additional 53,351,117 shares of Series B convertible preferred stock under the same terms and conditions of the initial offering.

We have determined that our obligation to issue, and our investor's obligation to purchase, additional shares of convertible preferred stock represented a freestanding financial instrument, which we accounted for as a liability. The freestanding financial instrument liability was initially recorded at fair value, with fair value changes recognized at each balance sheet date as increases or decreases to other income (expense), net in the statement of operations. At the time of the exercise of the option which, pursuant to its terms, must occur prior to an IPO, we will remeasure the obligation to fair value with the change recognized in other income (expense), net, in the statements of operations and immediately reclassify the liability to temporary equity.

*Estimated Fair Value of Convertible Preferred Stock Warrants*

Warrants for shares that are contingently redeemable, such as our Series B convertible preferred stock, are accounted for as freestanding financial instruments. These warrants are classified as liabilities on our consolidated balance sheets and are recorded at their estimated fair value. At the end of each reporting period, changes in the estimated fair value during the period are recorded as a component of other income (expense), net. We will continue to adjust these liabilities for changes in fair value until the earlier of the expiration or the exercise of the warrants.

*Stock-Based Compensation*

We measure stock-based awards granted to our employees and nonemployee directors at fair value on the date of grant and recognize the corresponding compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue stock options and restricted stock with only service-based vesting conditions and record the expense for these awards using the straight-line method. We have historically granted stock options with exercise prices no less than the fair market value of our common stock as of the date of grant.

We measure stock-based awards granted to nonemployee consultants at the fair value of the award on the date at which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such nonemployee consultants until completed. At the end of each financial reporting period prior to the completion of the service, the fair value of these awards is re-measured using, for options, the then-current fair market value of our common stock and updated assumptions in the Black-Scholes option-pricing model and using, for restricted stock, the then-current fair market value of our common stock.

The fair value of each stock option grant is estimated using the Black-Scholes option-pricing model. We are a private company and lack company-specific historical and implied volatility information. Therefore, we estimate our expected volatility based on the historical volatility of our publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price. The expected term of our options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options, while the expected term of our options granted to consultants and nonemployees has been determined based on the contractual term of the options. The risk-free interest rate is determined by reference to the United States Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

The assumptions we used to determine the fair value of stock options granted to employees and directors are as follows, presented on a weighted average basis:

	Year Ended December 31,	
	2013	2014
Risk-free interest rate	0.85 - 1.90%	0.85 - 1.97%
Expected term of options (in years)	6.0	5.0 - 6.25
Expected volatility	70.0%	70.0%
Dividend yield	0.0%	0.0%

These assumptions represented our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates when valuing our stock options, our stock-based compensation expense could be materially different. We recognize compensation expense for only the portion of awards that are

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expected to vest. In developing a forfeiture rate estimate for pre-vesting forfeitures, we have considered our historical experience of actual forfeitures. If our future actual forfeiture rate is materially different from our estimate, our stock-based compensation expense could be significantly different from what we have recorded in the current period.

Stock-based compensation expense totaled \$749,000 and \$1.1 million for the years ended December 31, 2013 and 2014, respectively, and \$481,000 and \$292,000 for the six months ended June 30, 2014 and 2015, respectively. We record stock-based compensation expense as a component of research and development expenses or general and administrative expenses, depending on the function performed by the grantee. For the years ended December 31, 2013 and 2014, and the six months ended June 30, 2014 and 2015, we allocated stock-based compensation as follows:

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
	(in thousands)		(unaudited)	
Research and development	\$ 166	\$ 202	\$ 78	\$ 43
General and administrative	583	885	403	249
Total	<u>\$ 749</u>	<u>\$ 1,087</u>	<u>\$ 481</u>	<u>\$ 292</u>

As of June 30, 2015, we had \$208,000 of total unrecognized stock-based compensation expense, which we expect to recognize over a weighted-average remaining vesting period of approximately 1.29 years. In future periods, our stock-based compensation expense is expected to increase as a result of recognizing our existing unrecognized stock-based compensation for awards that will vest and as we issue additional stock-based awards to attract and retain our employees.

#### *Determination of the Fair Market Value of Common Stock*

We are a privately held company with no active public market for our common stock. Therefore, in the absence of a public trading market for our common stock, our board of directors has determined the fair market value of our common stock at various dates, with input from management, considering our most recently available third-party valuations of common stock and its assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to determine the fair market value of our common stock in connection with our accounting for granted stock options and shares of restricted stock, as the fair market value of our common stock will be its trading price on The NASDAQ Capital Market.

We have periodically determined the fair market value of our common stock at various dates using contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were performed using a hybrid method, which used market approaches to determine our enterprise value. The hybrid method is a probability-weighted expected return method where the equity value in one or more of the scenarios is calculated using an option-pricing method. We selected the method based on availability and the quality of information to develop the assumptions for the methodology. We performed these contemporaneous valuations, with the assistance of a third-party valuation specialist, as of July 11, 2014 and December 31, 2014. In addition, our board of directors considered various

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objective and subjective factors, along with input from management, to determine the fair market value of our common stock as of each grant date, including the following:

- prices at which we sold shares of our preferred stock and the superior rights and preferences of our preferred stock relative to our common stock;
- the progress of our research and development programs, including the status of non-clinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- our financial condition, including cash on hand;
- our historical and forecasted performance and operating results;
- the composition of, and changes to, our management team and board of directors;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as a sale of our company or an initial public offering, or IPO, given prevailing market conditions;
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry;
- external market conditions affecting the biopharmaceutical industry; and
- trends within the biopharmaceutical industry.

The assumptions underlying these valuations represent management's determinations, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

Following the closing of this offering, the fair market value of our common stock will be determined based on the quoted market price of our common stock.

The following table summarizes by grant date the number of shares subject to options granted since January 1, 2014, the per share exercise price of the options, the fair market value of common stock underlying the options on date of grant and the per share fair value of the options:

<u>Date of Issuance</u>	<u>Number of Shares Underlying Options Granted</u>	<u>Exercise Price per Share</u>	<u>Fair Market Value per Common Share</u>	<u>Fair Value of Options per Share</u>
5/13/2014	44,640	\$ 10.08	\$ 5.32	\$ 2.52
7/10/2014	78,491	\$ 10.08	\$ 5.32	\$ 2.52 - 2.80
7/10/2014	54,353	\$ 16.80	\$ 5.32	\$ 1.68
4/30/2015	3,571	\$ 6.44	\$ 5.04	\$ 2.80
6/2/2015	69,285	\$ 6.16	\$ 5.04	\$ 2.52 - 2.80

In valuing our common stock, the board of directors determined the equity value of our business by considering a number of valuation approaches and allocation methodologies. Valuation techniques considered included the Current Value Method, the Probability-Weighted Expected Return Method, or PWERM, the Option Pricing Method, or OPM, and the Hybrid Method. Given the range of possible financing and exit events that existed at the time we completed our valuations, we concluded the PWERM to be the most appropriate for purposes of valuing our common stock given our expected time to a liquidity event, subjectivity with regards to estimating possible proceeds from a future liquidation event and subjectivity with regards to the ability to estimate the probability of an IPO, sale or other financing events. The PWERM explicitly considers the various terms of our investor related

documents, including various rights of each class of our stock, at the date of the liquidity event when those rights will either be executed or abandoned. Under the PWERM, the value of each class of our stock is estimated using a probability-weighted analysis of the present value of the returns afforded to our stockholders under each of our possible future exit scenarios. The scenarios included within the PWERM analysis included IPOs, a sale transaction, remaining private and dissolution.

Discrete future outcomes considered under the PWERM included non-IPO market based outcomes as well as IPO scenarios. In the non-IPO scenarios, a large portion of the equity value is allocated to the preferred stock to incorporate higher aggregate liquidation preferences. In the IPO scenarios, the equity value is allocated pro rata among the shares of common stock and each series of preferred stock, which causes the common stock to have a higher relative value per share than under the non-IPO scenario. The fair value of the enterprise determined using the IPO and non-IPO scenarios will be weighted according to the board of directors' estimate of the probability of each scenario.

Once our common stock commences trading it will not be necessary to determine the fair value of new stock-based awards pursuant to the methodology described above.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, *Revenue From Contracts With Customers*, or ASU 2014-09. Pursuant to this update, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The amendments in this update are currently effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period, and are to be applied retrospectively, or on a modified retrospective basis. Early application is not permitted. In July 2015, the FASB approved a one year deferral of the effective date for annual reporting periods beginning after December 15, 2017 with early adoption permitted for annual periods beginning after December 15, 2016. We are currently evaluating the impact of adopting ASU 2014-09 on our financial statements.

In June 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*, or Topic 915. The guidance set forth in Topic 915 is intended to reduce the overall cost and complexity associated with financial reporting for development stage entities without reducing the availability of relevant information. The FASB also believes the changes will simplify the consolidation accounting guidance by removing the differential accounting requirements for development stage entities. As a result of these changes, there no longer will be any accounting or reporting differences in generally accepted accounting principles, or GAAP, between development stage entities and other operating entities. For organizations defined as public business entities, the presentation and disclosure requirements in Topic 915 will no longer be required starting with the first annual period beginning after December 15, 2014, including interim periods therein. Early application is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities). We early adopted this guidance during the year ended December 31, 2014 and, as a result, we no longer present inception-to-date information about the statements of operations, cash flows, and stockholders' deficit.

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In August 2014, FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASU 2014-15. ASU 2014-15 explicitly requires a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016, although early application is permitted. We are currently evaluating the potential impact of the adoption of this standard, but believe its adoption will have no impact on our financial position, results of operations or cash flows.

In November 2014, the FASB issued ASU No. 2014-16, *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share is more akin to Debt or to Equity*, or ASU 2014-16. ASU 2014-16 clarifies how current GAAP should be interpreted in evaluating the economic characteristics and risks of a host contract in a hybrid financial instrument that is issued in the form of a share. Specifically, ASU 2014-16 provides that an entity should consider all relevant terms and features, including the embedded derivative feature being evaluated for bifurcation, in evaluating the nature of the host contract. ASU 2014-16 is effective for public companies for fiscal years and interim periods within those fiscal years beginning after December 15, 2015 with early adoption permitted. We adopted this guidance for the year ended December 31, 2014 and have properly applied it to hybrid financial instruments.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*, or ASU 2015-03. ASU 2015-03 requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The standard also aligns the GAAP presentation with International Financial Reporting Standards and will remedy the long-standing conflict with the guidance in FASB Concepts Statement No. 6, *Elements of Financial Statements*, which indicates that debt issuance costs do not meet the definition of an asset, because they provide no future economic benefit. ASU No. 2015-03 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis. The adoption of this guidance during the six months ended June 30, 2015 did not have a material impact on our balance sheets.

### **JOBS Act**

The JOBS Act contains provisions that, among other things, reduce reporting requirements for an "emerging growth company." As an emerging growth company, we have elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, 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.

### **Internal Control Over Financial Reporting**

Assessing our staffing and training procedures to improve our internal control over financial reporting is an ongoing process. We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and are therefore not required to make an assessment of the effectiveness of our internal control over financial reporting. As a result, our management did not perform an evaluation of our internal control over financial reporting as of December 31, 2014. Further, our independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting.

## Results of Operations

### Comparison of Six Months Ended June 30, 2015 and 2014

#### Research and development

Research and development expenses decreased by \$2.0 million, from \$5.6 million for the six months ended June 30, 2014 to \$3.6 million for the six months ended June 30, 2015. This decrease resulted from a \$2.5 million decrease in external research and development costs due to preparations for two clinical trials in 2014, partially offset by a \$1.0 million expense during the six months ended June 30, 2015 related to the licensing of CERC-501. There was also a decrease of \$420,000 in the six months ended June 30, 2015 as compared to the same period in 2014 related to personnel compensation and benefits due to a reduction in headcount. We expect future research and development expenses to increase due to the continued development of CERC-301 and our COMTi platform, including CERC-406, as well as the commencement of the development of CERC-501.

The following table summarizes our research and development expenses for the six months ended June 30, 2014 and 2015:

	Six Months Ended June 30,	
	2014	2015
	(in thousands)	
CERC-301	\$ 4,093	\$ 1,552
COMTi	314	158
CERC-501	—	1,103
Personnel-related costs	1,091	671
Other research and development	113	115
	<u>\$ 5,611</u>	<u>\$ 3,599</u>

#### General and Administrative

General and administrative expenses increased by \$0.1 million for the six months ended June 30, 2015 compared to the same period in 2014. During the six months ended June 30, 2015 our consulting and professional fees were \$177,000 higher than the six months ended June 30, 2014 due to higher costs for financial consultants primarily in conjunction with our proposed initial public offering, and recruiter fees. In addition, marketing and business development expense was \$71,000 higher for the six months ended June 30, 2015 as compared to the same period in 2014.

#### Change in Fair Value of Warrants and Investor Rights Obligation

We recognized a loss on the change in fair value of our warrants and Investor Rights Obligation of \$0.3 million during the six months ended June 30, 2015 as compared to a gain of \$0.4 million during the same period in 2014. The change during the six months ended June 30, 2015 in fair value of warrants and Investor Rights Obligation is primarily due to the issuance of warrants for shares of Series B convertible preferred stock and our Investor Rights Obligation during the third quarter of 2014 and their respective changes in fair value.

The change during the six months ended June 30, 2014 in fair value was due to the gain recognized from marking the warrants for shares of Series A-1 convertible preferred stock to market.

#### Interest Expense, Net

Interest expense decreased by \$0.4 million for the six months ended June 30, 2015 compared to the same period in 2014. The decrease is primarily due to the amortization of debt discounts in



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connection with our financing activities in 2014. This was offset for interest paid under our secured term loan facility that was entered into in August 2014 during the six months ended June 30, 2015.

**Comparison of Years Ended December 31, 2014 and 2013***Research and development*

Research and development expenses increased by \$3.3 million, from \$8.9 million for the year ended December 31, 2013 to \$12.2 million for the year ended December 31, 2014. During 2013, we had a partial year of FP01 clinical trial costs and minimal costs in 2014 due to the completion of the FP01 clinical trials. In 2014, we continued the development of CERC-301 and our COMTi platform. In the aggregate, these external research and development costs increased by \$3.4 million. There was also an increase of \$456,000 related to compensation and benefits related to personnel and related costs in 2014 as compared to 2013. Other research and development costs decreased by \$569,000 due primarily to the inclusion of costs in 2013 for a research project on a compound that was discontinued. We expect future research and development expenses to increase due to the continued development of CERC-301 and our COMTi platform, including CERC-406, as well as the commencement of the development of CERC-501.

The following table summarizes our research and development expenses for the years ended December 31, 2013 and 2014:

	Year Ended December 31,	
	2013	2014
	(in thousands)	
FP01	\$ 2,990	\$ 28
CERC-301	2,717	8,711
COMTi	353	761
Stock-based compensation	166	202
Other personnel-related costs	1,857	2,277
Other research and development	831	262
	<u>\$ 8,914</u>	<u>\$ 12,241</u>

*General and Administrative*

General and administrative expenses increased by \$0.9 million for the year ended December 31, 2014 compared to the same period in 2013. Compensation and benefits expenses in 2014 were \$0.6 million higher than in 2013 primarily due to option awards that were fully vested at the time of the award. We also incurred \$0.6 million in additional consulting and professional fees in connection with the initial submission of our registration statement. These increases were offset by a \$0.3 million reduction in marketing and business development expenses in 2014.

*Change in Fair Value of Warrants and Investor Rights Obligation*

We recognized a loss on the change in fair value of our warrants and Investor Rights Obligation of \$0.1 million during the year ended December 31, 2013 compared to a gain of \$2.3 million in 2014. The change in fair value of warrants and Investor Rights Obligation is primarily due to the issuance of warrants for shares of Series B convertible preferred stock and our Investor Rights Obligation in 2014 and their respective changes in fair value.

*Interest Expense, Net*

Interest expense increased by \$1.2 million for the year ended December 31, 2014 compared to the same period in 2013. The increase is primarily due to the amortization of debt discounts, premiums, and deferred financing fees in connection with our financing activities in 2014 as well as the interest paid under our secured term loan facility that was entered into in August 2014.

**Liquidity and Capital Resources**

We have devoted most of our cash resources to research and development and general and administrative activities. Since our inception, we have incurred net losses and negative cash flows from our operations. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek marketing approval for, our product candidates. We incurred net losses of \$6.2 million in the six months ended June 30, 2015 and \$13.0 million and \$16.1 million for the years ended December 31, 2013 and 2014, respectively. At June 30, 2015, we had an accumulated deficit of \$49.2 million, a working capital deficit of \$1.0 million and cash and cash equivalents of \$6.1 million. To date, we have not generated any revenues from the sale of products and we do not anticipate generating any revenues from the sale of our product candidates for the foreseeable future. Historically, we have financed our operations principally through private placements of common and convertible preferred stock, convertible and nonconvertible debt. Through June 30, 2015 we have received aggregate net proceeds of \$51.1 million primarily from the issuance of common and convertible preferred stock and debt. We anticipate funding our operations over the next several years from further sales of debt and equity securities, including this offering.

**Cash Flows**

The following table summarizes our cash flows for the six months ended June 30, 2014 and 2015:

	<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2015</b>
	<b>(in thousands)</b>	
Net cash (used in) provided by:		
Operating activities	\$ (4,451)	\$ (4,800)
Investing activities	—	—
Financing activities	1,250	(799)
Net (decrease) in cash and cash equivalents	<u>\$ (3,201)</u>	<u>\$ (5,599)</u>

*Net cash used in operating activities*

Net cash used in operating activities was \$4.5 million for the six months ended June 30, 2014 and consisted primarily of a net loss of \$7.7 million offset by a non-cash increase of \$481,000 of stock-based compensation and a \$2.1 million increase in accounts payable and accrued expenses due primarily to increased clinical trial activities.

Net cash used in operating activities was \$4.8 million for the six months ended June 30, 2015 and consisted primarily of a net loss of \$6.2 million and an increase in our net operating assets of \$0.6 million primarily due to the timing of payments related to our personnel and clinical trial activities. The loss was also offset by \$0.7 million in non-cash charges that are primarily related to non-cash interest and a \$0.3 million non-cash loss on the change in fair value of our warrants and Investor Rights Obligation liabilities.

[Table of Contents](#)*Net cash provided by and (used in) financing activities*

Net cash provided by and used in financing activities was \$1.25 million and (\$0.8) million for the six months ended June 30, 2014 and June 30, 2015, respectively, and related to proceeds from the bridge note financing in 2014 and IPO-related deferred financing costs and payments on outstanding debt obligations in 2015.

The following table summarizes our cash flows for the years ended December 31, 2013 and 2014:

	Year Ended December 31,	
	2013	2014
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (11,485)	\$ (15,518)
Investing activities	(29)	(20)
Financing activities	5,416	23,859
Net decrease (increase) in cash and cash equivalents	<u>\$ (6,098)</u>	<u>\$ 8,321</u>

*Net cash used in operating activities*

Net cash (used in) operating activities was \$11.5 million for the year ended December 31, 2013 and consisted primarily of a net loss of \$13.0 million offset by a non-cash increase of \$749,000 of stock-based compensation and a \$1.1 million increase in accounts payable and accrued expenses due primarily to increased clinical trial activities.

Net cash used in operating activities was \$15.5 million for the year ended December 31, 2014 and consisted primarily of a net loss of \$16.1 million, a \$2.3 million non-cash gain on the change in fair value of our warrants and Investor Rights Obligation liabilities, and a decrease in our net operating assets of \$0.4 million primarily due to the timing of payments related to our personnel and clinical trial activities. These decreases were offset by \$3.2 million in non-cash charges that are primarily related to stock-based compensation expense, non-cash interest, and the expensing of offering costs that were initially reflected as a financing cash outflow of \$1.1 million, \$1.0 million and \$1.1 million, respectively.

*Net cash used in investing activities*

Net cash used in investing activities for the years ended December 31, 2013 and 2014 was \$29,000 and \$20,000, respectively. Cash used in investing activities primarily consisted of purchases of fixed assets related to purchases of furniture and computer equipment.

*Net cash provided by financing activities*

Net cash provided by financing activities was \$5.4 million for the year ended December 31, 2013, which was primarily due to net proceeds of \$6.1 million received from the sale and issuance of our Series A-1 convertible preferred stock and warrants offset by \$0.7 million in payments of deferred financing fees related to our IPO efforts.

Net cash provided by financing activities was \$23.9 million for the year ended December 31, 2014, which was primarily due to the proceeds received from our convertible debt, demand notes, and Series B convertible preferred stock equity issuance aggregating \$17.3 million and \$7.4 million from a term loan. We also paid \$0.4 million in financing fees related to the equity and debt financings and \$0.4 million for IPO-related deferred financing costs.

## Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our cash expenditures to increase in the near term as we fund our future development of CERC-301, CERC-501 and our COMTi platform, including preclinical development for CERC-406. Following this offering, we will be a publicly traded company and will incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules adopted by the Securities and Exchange Commission, or SEC, and the NASDAQ Stock Market, requires public companies to implement specified corporate governance practices that are currently inapplicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We may also acquire or in-license new product candidates.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents as of June 30, 2015, will enable us to fund our operating expenses and capital expenditure requirements through the end of 2016. Each of our product candidates are still in the early stages of clinical and preclinical development and the outcome of these efforts is uncertain. We cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may generate revenue. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and exploring the possibility of entering into collaboration arrangements.

We will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we raise additional funds through collaboration and licensing agreements with third parties, it may be necessary to relinquish valuable rights to our product candidates, technologies or future revenue streams or to grant licenses on terms that may not be favorable to us. Our future capital requirements will depend on many forward-looking factors, including:

- the progress and results of the Phase 2 clinical program for CERC-301 and changes to our development plan with respect to CERC-301, if any;
- the progress and results of the clinical trials being conducted, or contemplated being conducted, for CERC-501 and changes to our development plan with respect to CERC-501, if any;
- our plan and ability to enter into collaborative agreements for the development and commercialization of our product candidates;
- the number and development requirements of any other product candidates that we pursue;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs, timing and outcome of regulatory review of our product candidates or any future product candidates, both in the United States and in territories outside the United States;

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- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for any of our product candidates for which we receive marketing approval;
- the costs and timing of any product candidate acquisition or in-licensing opportunities;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and in territories outside the United States; and
- the timing and success of this offering.

Please see "Risk Factors" for additional risks associated with our substantial capital requirements.

### **Contractual Obligations and Commitments**

The following is a summary of our long-term contractual cash obligations as of December 31, 2014 (in thousands):

<b>Contractual Obligation(1)</b>	<b>Total</b>	<b>Less than One Year</b>	<b>1 - 3 Years</b>	<b>3 - 5 Years</b>	<b>More than 5 Years</b>
Long Term Debt Obligations(2)	\$ 8,428	\$ 2,633	\$ 5,795	\$ —	\$ —
Operating lease obligations(3)	612	147	306	159	—
<b>Total contractual obligations</b>	<b>\$ 9,040</b>	<b>\$ 2,780</b>	<b>\$ 6,101</b>	<b>\$ 159</b>	<b>\$ —</b>

- (1) This table does not include any contingent milestone or royalty payments that may become payable to third parties under license agreements because the timing and likelihood of such payments are not known.
- (2) Amount represents principal and interest cash payments over the life of the debt obligations, including anticipated interest payments that are not recorded on our balance sheet.
- (3) Operating lease obligations reflect our obligations pursuant to the terms of a lease agreement entered into on August 8, 2013 for our office space located in Baltimore, Maryland.

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

We do not have any off-balance sheet arrangements, as defined by applicable SEC rules and regulations.

### **Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. We had cash and cash equivalents of \$3.4 million, \$11.7 million and \$6.1 million as of December 31, 2013, December 31, 2014, and June 30, 2015, respectively, consisting of cash and money market funds. We do not enter into investments for trading or speculative purposes. We do not believe an immediate 10% increase in interest rates would have a material effect on the fair market value of our cash and money market funds, and accordingly we do

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not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

We contract with CROs, clinical research organizations and contract manufacturers globally. We may be subject to fluctuations in foreign currency rates in connection with some of these agreements. To date, we have not incurred material effects from foreign currency changes on these contracts. Transactions denominated in currencies other than the United States dollar are recorded based on exchange rates at the time such transactions arise.

## BUSINESS

### Overview

We are a clinical-stage biopharmaceutical company with the goal of becoming a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. We have a portfolio of clinical and preclinical compounds that we believe are best-in-class due to their unique mechanism of action and where human proof of concept has been established for the compound or the target. We are currently pursuing regulatory approval of three product candidates: CERC-301, CERC-501 and CERC-406.

CERC-301 is currently in Phase 2 development as an oral, adjunctive treatment of patients with major depressive disorder, or MDD, who are failing to achieve an adequate response to their current antidepressant treatment and are severely depressed. We received fast track designation by the Food and Drug Administration, or FDA, in November 2013 for CERC-301 for the treatment of MDD. CERC-301 belongs to a class of compounds known as antagonists, or inhibitors, of the N-methyl-D-aspartate, or NMDA, receptor, a receptor subtype of the glutamate neurotransmitter system that is responsible for controlling neurological adaptation. We believe CERC-301 will be a "first-in-class" medication that will cause a significant reduction in depression symptoms in a matter of days, as compared to weeks or months with conventional therapies, because it selectively blocks the NMDA receptor subunit 2B, or NR2B, which we believe provides rapid and significant antidepressant activity without the adverse side effect profile of non-selective NMDA receptor antagonists. We are also currently developing CERC-501, which is in Phase 2 development. We intend to first develop CERC-501 for adjunctive treatment of MDD and for substance use disorders (e.g., nicotine, alcohol, and/or cocaine). If we receive approval for CERC-501 for adjunctive treatment of MDD and for substance use disorders, we plan to further develop CERC-501 for the concurrent treatment of MDD and substance use disorders, or co-occurring disorders. CERC-501 was acquired in February 2015, and is a potent and selective kappa opioid receptor, or KOR, antagonist. KORs are believed to play key roles in modulating stress, mood and addictive behaviors, which form the basis of co-occurring disorders. We believe that proof of concept of KOR antagonism for the adjunctive treatment of MDD is supported by Alkermes plc's, or Alkermes, Phase 2 results for ALKS-5461, which is believed to be acting as a functional kappa antagonist. Alkermes has reported positive Phase 2 results for ALKS-5461 as an adjunctive antidepressant in MDD subjects and has initiated a Phase 3 development program. We are preparing to initiate a clinical study to evaluate the effect of CERC-501 on aspects of tobacco withdrawal and reinstatement by the first half of 2016. In addition we are considering conducting a Phase 2 clinical study in inadequately treated subjects with MDD currently on antidepressants, with an initiation date in the second half of 2016. Thereafter we intend to pursue additional studies focused on substance use disorders, the adjunctive treatment of MDD and, depending on marketing approval, the treatment of co-occurring disorders. CERC-406 is our preclinical lead candidate from our proprietary platform of compounds that inhibit catechol-O-methyltransferase, or COMT, within the brain, which we refer to as our COMTi platform. We anticipate developing CERC-406 for the treatment of residual cognitive impairment symptoms in patients with MDD.

Members of our management team have extensive pharmaceutical product development and commercialization experience and they have played key roles in the development or commercialization of Prozac®, Zyprexa®, Lyrica®, Cymbalta®, Neurontin® and Abilify®, each of which is a neuroscience product that has generated over \$1.0 billion of annual revenues. Collectively, our officers and directors have contributed to the submission of numerous Investigational New Drug Applications, or INDs, and nine New Drug Applications, or NDAs, to the FDA. Leveraging the experience of our management team, within the last 24 months we obtained IND clearance and received fast track designation for CERC-301 from the FDA, completed two clinical trials of CERC-301, selected CERC-406 as our preclinical lead candidate from our COMTi platform and, most recently, broadened our clinical pipeline by in-licensing CERC-501.

## Our Strategy

Our goal is to be a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. We systematically identify platforms and product candidates for which human proof of concept exists in the intended indication, for either the target or the compound, and for which biomarkers are available to measure therapeutic response. We target conditions where we believe current treatments fail to address unmet medical needs, and where we can apply clinical strategies to increase efficacy signal detection. These strategies include using personalized therapeutic approaches and placebo mitigation techniques to facilitate regulatory approval for our product candidates.

Our strategic objectives include:

- ***Rapidly Advance the Clinical Development of CERC-301.*** We are currently developing CERC-301 as an oral, adjunctive medication for patients with MDD who are failing to achieve an adequate response to their current antidepressant treatment and are severely depressed. We have recently completed a seven day, inpatient exploratory Phase 1 study of CERC-301 in 48 healthy volunteers in order to determine maximal dose range, in addition to an outpatient Phase 2 clinical trial of an 8 mg daily dose of CERC-301 as an adjunctive therapy in 137 subjects who were severely depressed despite ongoing antidepressant treatment and, who have recently experienced active suicidal ideation. In the third quarter of 2015, we initiated a Phase 2 efficacy study for CERC-301 in order to evaluate doses greater than 8 mg and a revised dosage regimen. If we demonstrate safety and efficacy in these and subsequent Phase 2 and 3 studies, we will consider also initiating separate development programs in other indications, such as active suicidal ideation, bipolar depression and other neuropsychiatric conditions.
- ***Rapidly Advance the Clinical Development of CERC-501.*** We plan to initiate a proof of concept clinical trial in nicotine dependence by first half of 2016, which will provide us with the opportunity to evaluate the effect of CERC-501 on tobacco reinstatement behavior and assess subjects' craving, mood and anxiety during abstinence periods. We also expect to receive data from three additional studies concerning CERC-501, in cocaine addiction, treatment resistant depression, or TRD, and the inability to experience pleasure, or anhedonia, two of which are being conducted under the auspices of the National Institute of Mental Health, or NIMH. Thereafter we are considering conducting a Phase 2 clinical study in inadequately treated subjects with major depressive disorder currently on antidepressants, with an initiation date in the second half of 2016. If these studies are successful, we plan to develop CERC-501 as a treatment of substance use disorders, a once-a-day, oral adjunctive treatment of MDD, and, depending on marketing approval, the treatment of co-occurring disorders.
- ***Advance CERC-406 into IND-enabling Studies.*** We anticipate developing CERC-406 as a "first-in-class," oral, adjunctive treatment for patients with residual cognitive impairment symptoms suffering from MDD. We expect to complete IND-enabling studies and submit an IND for CERC-406 by the first half of 2017.
- ***Use our COMTi Platform to Build a Pipeline of Product Candidates for Conditions Where Impaired Executive Function is a Core Symptom.*** By targeting COMT inhibition, for which human proof of concept in multiple conditions exists for the COMT inhibition class of drugs, we believe we have the ability to address the impairment of executive function in a highly specific manner, guided by biomarkers and pharmacogenomics. Our COMTi platform, which we licensed from Merck & Co., Inc. and its affiliates, or Merck, provides exclusive access to a library of approximately 1,800 compounds that we believe may penetrate the nervous system and preferentially inhibit COMT in the brain. In 2015 and 2016, in addition to progressing the development of CERC-406, we intend to establish the data set necessary to select additional lead candidates from the library for treatment of various conditions where impaired executive



function is a core symptom. In addition to compounds that we may develop on our own, we are exploring early development collaborations with third parties on an indication-specific basis in order to maximize the value of our COMTi platform.

- **Establish Specialty Segment Commercialization and Marketing Capabilities in the United States.** We intend to selectively retain commercialization rights for certain of our product candidates and to build specialty commercialization capabilities in the United States, which we may complement with co-promotion agreements with partners. We may also seek to commercialize any of our approved products outside of the United States, although we plan to do so with one or more collaborators.
- **Establish Collaborations to Maximize Value.** Collaborations, through licenses or strategic partnerships, may provide access to the considerable scientific, development, regulatory and commercial capabilities of biopharmaceutical corporations, potentially providing us with additional infrastructure to more efficiently develop and commercialize assets in our product candidate portfolio. Our selection criteria for potential partners include market presence in complementary areas and geographies, in addition to a demonstrated ability to contribute to the creation of the highest quality data sets and registration materials for submission to regulatory authorities when we seek marketing approval for our product candidates.
- **Expand our Product Candidate Portfolio Through In-Licensing and Strategic Acquisitions.** In migrating away from the centralized research and development model of the past, many major pharmaceutical companies have deemphasized their neuroscience discovery and development programs in recent years. Given our focus and expertise, these programs may represent compelling acquisition opportunities. We believe we have the ability to identify, evaluate and procure valuable product programs that are consistent with our goal of becoming a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. We plan to continue to leverage these opportunities to expand our product candidate portfolio in a fashion that fits within our core strategy and enhances our overall value.

## Product Pipeline

The following table summarizes key information about our three product candidates and further detail regarding each product candidate follows:

<u>Product Candidate / Platform</u>	<u>Potential Indication(s)</u>	<u>Stage of Development</u>	<u>Anticipated Milestones</u>
<b>CERC-301</b>	Adjunctive treatment of MDD with rapid onset	Phase 2	Data in the second half of 2016
<b>CERC-501</b>	Substance use disorders Adjunctive treatment of MDD Co-occurring disorders	Phase 2	Data in the second half of 2016
<b>CERC-406</b>	Residual cognitive impairment symptoms in MDD	Preclinical	IND submission anticipated in the first half of 2017

**CERC-301**

*Current Depression Treatment Paradigm and Limitations*

Depression is one of the most common serious medical and psychiatric disorders, with greater than 150 million adults worldwide suffering from MDD at any given time, according to a 2003 report by the World Health Organization, or WHO, titled *Investing In Mental Health*. According to the U.S. National Comorbidity Survey Replication published in 2007, or the NCS-R, more than 16 million adults in the United States, which represents approximately 6.7% of its entire adult population, will suffer from a MDD episode in a 12 month period. Furthermore, according to the NCS-R, approximately 45% of these cases can be classified as severe, and suicide is often a grave complication associated with depression. Studies have shown that approximately 50% to 70% of severely depressed patients have experienced suicidal ideation. Over time, the understanding of psychiatric and neurological disorders, as well as their biological underpinnings, has evolved based on a combination of clinical and pre-clinical research. Over the past 50 years, many depression therapies and hypotheses have primarily been based on changing the levels of monoamine neurotransmitters, such as serotonin, norepinephrine and dopamine, in the brain. Manipulating these neurotransmitters impacts mood, but monoamine antidepressants are slow in onset, requiring multiple weeks for patients to obtain a response and patients may suffer from sexual dysfunction and other side effects from such treatment.

Numerous studies have shown that many patients do not respond to their initial antidepressant therapy. For example, according to a 2006 report titled *Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR-D Report*, or the STAR-D Report, 51.4% of patients failed to respond, defined as achieving a 50% reduction in symptoms, and only 36.8% became symptom free, or achieved remission, after their initial 12-week treatment course with monoamine antidepressants. As such, physicians commonly will switch patients' antidepressants to manage depression, and patients may require two or three courses of treatment, before achieving satisfactory relief. The depression may persist following a course of treatment and additional medications may need to be used adjunctively. These adjunctive agents may include atypical antipsychotics, like aripiprazole and quetiapine, or other agents such as bupropion, and lithium. While certain patients experience improvement in their depressive symptoms when these additional therapies are added to their existing treatments, many do not. For example, according to a study published by Dr. Robert Berman and others in 2007, entitled *The Efficacy and Safety of Aripiprazole as Adjunctive Therapy in Major Depressive Disorder: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study*, only 32.4% of patients with treatment resistant depression responded to six weeks of adjunct treatment of the atypical antipsychotic aripiprazole.

According to the IMS Institute for Healthcare Informatics' 2012 report titled *The Use of Medicines in the United States: Review of 2011*, over 264 million prescriptions totaling \$11 billion were filled for depression in the United States in 2011. According to the STAR-D Report most marketed depression therapies are subject to significant limitations, including:

- **Time to therapeutic response.** Current monoamine antidepressants are slow in onset, allowing depressive symptoms to persist for multiple weeks before patients experience the onset of the drugs' therapeutic effect; full effect is frequently not seen until 12 weeks.
- **High rates of treatment failures and low rates of remission.** Even with the widespread availability of serotonin reuptake inhibitors, or SSRIs, or serotonin norepinephrine reuptake inhibitors, or SNRIs, MDD remains a leading cause of disability in the world. According to the STAR-D Report, which was funded by the NIMH, despite four courses of different antidepressant medications, 33% of patients did not achieve remission.

- **Side effects.** Common side effects seen with current depression therapies include gastrointestinal disturbance, dizziness, drowsiness, insomnia and sexual dysfunction. A common symptom of depression is a loss of libido. Compounding this issue, although most side effects associated with SSRIs and SNRIs subside within the first few weeks of treatment, sexual dysfunction often persists throughout the course of treatment. According to the STAR-D Report, many patients who experience side effects discontinue treatment. In addition, currently used adjunctive treatments include antipsychotic agents which have both efficacy and treatment-limiting side effects, including weight gain, increased risk of diabetes and cardiovascular risk.

#### *Emergence of NMDA Receptor Antagonists as Antidepressants*

Recently, a new class of antidepressant has emerged known as antagonists of the NMDA receptor, a receptor subtype of the glutamate neurotransmitter system that is responsible for controlling neurological adaptation. Research on ketamine, such as *A Randomized Trial of an N methyl D aspartate Antagonist in Treatment Resistant Major Depression* study conducted from November 2004 to September 2005 by Dr. Carlos A. Zarate, Jr. and others, has provided evidence that NMDA antagonists can provide significant antidepressant mood effects within 24 hours of administration, acting as rapid acting antidepressants, or RAADs, in MDD and bipolar depression. Moreover, research has also demonstrated that ketamine causes a rapid reduction in suicidal ideation, in contrast to conventional antidepressants that may actually worsen suicidal ideation in children, adolescents, and young adults. We believe efficacy of the class is further supported by the off-label use of ketamine throughout the United States for treatment resistant bipolar depression and MDD.

Accumulating evidence, such as that discussed in an article published in 2014 by Ronald Duman and others, titled *Neurobiology of Stress, Depression, and Rapid Acting Antidepressants: Remodeling Synaptic Connections*, suggests that the antidepressant effect of this new class of antidepressant, as demonstrated by the study of ketamine, is associated with increasing synaptic connections in the brain, which is driven by increases in the synthesis of neuronal proteins. A messenger of this synthetic activity is brain derived neurotrophic factor, or BDNF, which we believe is increasingly considered to be a biomarker of depression and anti-depressant effect. BDNF levels have been found to be low in subjects with major depression compared to normal controls, correlate negatively with the severity of depression and recover to levels associated with normal subjects after successful antidepressant treatment. However, non selective NMDA antagonists such as ketamine have significant limitations. Ketamine is an anesthetic, is not approved for use as an antidepressant, and causes increases in heart rate and blood pressure, hallucinations and other psychological manifestations. In addition, psychiatric use of ketamine may be limited by the need for intravenous administration, the unapproved nature of the use of the drug for the sub chronic treatment of MDD and, as a result, the unknown safety profile, and the need for repeated infusions to maintain a treatment response. Ketamine is scheduled by the Drug Enforcement Administration or DEA, as a Schedule III controlled substance and is prone to abuse. The classification of ketamine as a Schedule III controlled substance means that manufacturers, distributors, and health care providers that handle or prescribe ketamine must, among other things, register with the DEA, keep accurate and complete records, take special precautions to secure the drug and prevent its loss or theft, and may need to periodically file reports with the DEA. These extra regulatory requirements may increase the cost of manufacturing, distributing and prescribing the drug.

Recent research has unveiled new insights into NMDA inhibition and the neurobiology of depression, and points to new classes of antidepressant medications such as antagonists of the NR2B subunit containing NMDA receptors. We believe that NR2B inhibitors, which work on the glutamate system by blocking only NR2B containing NMDA receptors, have the potential to provide rapid and significant antidepressant activity without many of the adverse side effects of ketamine and other non selective NMDA receptor antagonists, as demonstrated in clinical trial published in 2012, titled *Investigational NMDA Receptor Modulators for Depression*, conducted by B. Szezewczyk and others.

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According to a 2013 Decision Resources report, Unipolar Depression, patients suffering from MDD need more effective agents with a faster onset of action, a higher remission rate, better efficacy for comorbid symptoms and a better side effect profile than that of conventional monoamine drugs—all potential qualities of this new class of antidepressants.

### *Our Solution*

CERC-301 is a selective NR2B antagonist that we are currently developing as a "first-in-class," oral adjunctive medication for patients with MDD who are failing to achieve an adequate response to their current antidepressant treatment and are severely depressed. Furthermore, we believe CERC-301 will have a rapid onset of effect, be well tolerated and may have fewer side effects than the leading adjunctive treatments currently available, such as atypical antipsychotics, whose treatment efficacy is hindered by side effects such as weight gain and increased risk of diabetes. We expect that a drug with these attributes will lead to improved compliance and outcomes. We believe an antidepressant with rapid onset of effect can possibly provide its greatest benefit by quickly relieving suicidality, a risk factor for suicide. Studies have shown that approximately 50% to 70% of severely depressed patients have experienced suicidal ideation.

We licensed MK-0657, which is now known as CERC-301, from Merck and we believe that its selective NR2B inhibition has the potential to provide both the rapid antidepressant and suicidality reduction effects of non-selective NMDA antagonists, without many of their side effects, including increases in heart rate, blood pressure and mental status changes. Preliminary studies by Merck in healthy subjects failed to demonstrate clinically significant changes in mental status, however, modest changes in blood pressure were observed. As discussed in a 2009 article titled *Allosteric Modulators of NR2B-Containing NMDA Receptors: Molecular Mechanisms and Therapeutic Potential*, there is animal evidence that compounds selectively targeting NR2B receptor subunits, such as CERC-301, retain many of the beneficial effects while reducing many of the less desirable side effects of other NMDA antagonists.

We believe CERC-301 may have the following advantages over ketamine and other non-selective NMDA antagonists:

- minimal psychotomimetic effects, including hallucinations and intoxication;
- available in a convenient, oral dosing form suitable for daily or intermittent dosing; and
- ability to use for the prevention of a relapse of depression.

Additionally, we believe that CERC-301 may have the following advantages over conventional antidepressant therapies and currently approved adjunctive therapies:

- more rapid onset of action, including reduction in suicidality;
- higher rate of response and remission;
- reduced/absent sexual side-effect profile; and
- enhanced safety profile with respect to weight gain and increased risk of diabetes.

We received fast track designation for CERC-301 in November 2013 for the treatment of MDD. Fast track designation may help facilitate our development of CERC-301 and expedite the FDA's review of our marketing application as it may allow us to have more frequent meetings and correspondence with the FDA and the FDA may initiate review of sections of an NDA on a rolling basis before the application is complete.

*Our Program*

*Current Development Status*

In August 2012, Dr. Lobna Ibrahim and others at the NIMH reported the results of a study of CERC-301 titled *A Randomized, Placebo-Controlled, Crossover Pilot Trial of the Oral Selective NR2B Antagonist MK-0657 in Patients with Treatment-Resistant Major Depressive Disorder*, which we refer to as the 2012 NIMH Study. The study was conducted in five subjects with moderate TRD, as indicated by the subject's baseline scores on the Hamilton Depression Inventory 17 item scale, or HAMD-17. The 2012 NIMH Study demonstrated increases in plasma BDNF and a rapid onset of antidepressant effect of CERC-301 in TRD subjects without observations of significant changes in blood pressure or other side effects commonly seen with non-selective NMDA receptor antagonists. In 2014, we completed an exploratory inpatient pharmacokinetic, or PK, and pharmacodynamics, or PD, study in healthy volunteers, which we refer to as the PK/PD study, and a Phase 2 outpatient efficacy study for the adjunctive treatment of subjects with severe MDD who had recently experienced suicidal ideation. The PK/PD study provided evidence of safety and tolerability at daily doses up to 20 mg for seven days. Plasma levels of BDNF appeared to be higher in subjects receiving 16 mg and 20 mg doses of CERC-301 as compared to those subjects receiving placebo. In the Phase 2 study, CERC-301 was administered daily at a dose of 8 mg for 28 days as an adjunctive treatment to subjects' current medications. The primary endpoint was antidepressant effect at seven days as measured by the HAMD-17. The 8 mg dose was well tolerated, and there were no differences in mean blood pressure effects or heart rate between the treatment groups. However, the 8 mg dose of CERC-301 failed to achieve its primary endpoint and plasma BDNF levels did not change, which we believe suggests that drug exposure was inadequate. Given the safety and tolerability observed and the increases in BDNF seen at higher doses in the PK/PD study, we proposed to the FDA that doses higher than 8 mg can be tested in outpatient depression studies and that the potential of CERC-301 may be optimized with a higher dosing regimen. The FDA had no comments regarding the higher dosing regimen. We have recently initiated a Phase 2 study utilizing a higher dose and a revised dosing regimen, Clin301-203, with results becoming available in the second half of 2016.

*Study Clin301-203: A Randomized, Double-Blind, Placebo-Controlled Study of Intermittent Doses of CERC-301 in the Treatment of Subjects with Severe Depression Despite Antidepressant Treatment*

**Study Overview:** Clin301-203 is designed as a randomized, double blinded placebo-controlled trial in order to distinguish effects of drug treatment in an efficient and unbiased manner. We will evaluate the antidepressant effect of 12 mg and 20 mg doses of CERC-301 and enroll approximately 104 subjects with MDD who are currently experiencing a severe depressive episode despite stable ongoing treatment with either a SSRI or SNRI. This study will enable us to evaluate both the rapid onset of antidepressant effect and the duration of effect of CERC-301 over a seven and 14 day period after the last administration of the study drug.

**Study Design:** Clin301-203 includes two dose administrations seven days apart, followed by 14 days of observation, for a total study duration of 42 days. The primary objective of Clin301-203 is to evaluate the antidepressant effect of CERC-301, in 12 mg and 20 mg dosages, compared to placebo averaged between two and four days post-treatment with study drug, assessed by the 6-item unidimensional sub-set of the HAMD-17, or Bech-6. This approach will allow detection of acute drug effects as well as duration of drug effect. The key secondary objectives include evaluating the antidepressant effect of CERC-301 averaged between two and four days post-study drug administration, assessed by the HAMD-17 and the 7-item unidimensional subset of the HAMD-17, or the Santen-7. In addition, the antidepressant effects of CERC-301 at two, four and seven days after each dose and 14 days after last administration of study drug assessed by the Bech-6, Santen-7, HAMD-17, Clinically Useful Depression Outcome Scale-Anxiety Self Report, or CUDOS-A-SR, and Snaith-Hamilton Pleasure Scale Self Report, or SHAPS-SR will be evaluated. Antidepressant effect will also be assessed

using the Quick Inventory of Depressive Symptomatology Self Report, or QIDS-SR, Clinical Global Impression-Improvement, or CGI-I, and CGI-Severity, or CGI-S at seven days after each dose and 14 days after last administration of study drug. We will also evaluate the safety and tolerability of intermittent doses of CERC-301, and the relationship between baseline symptoms and rate/magnitude of response. Qualified site raters will administer clinician-administered scales and the subjects will administer self-reported scales. Clin301-203 will include a total of nine study visits, with four of the nine visits conducted remotely via telephone in order to mitigate the burden on the subjects.

**Enrollment Strategies:** The study will be performed in subjects with MDD currently experiencing a severe depressive episode despite current stable treatment with either a SSRI or SNRI. Subjects will be screened directly from psychiatric clinic referrals, from depression clinical study databases, and from advertising. Potential subjects will be screened by the study sites for all inclusion, exclusion and diagnostic criteria in order to determine eligibility for the study. Subjects will also be screened via an independent third party to determine eligibility.

**Adjunctive Therapy:** CERC-301 will be administered as an adjunctive therapy to current antidepressant treatment in subjects who have failed to adequately respond to their current therapy. We believe that initially pursuing approval as an adjunctive treatment addresses a key unmet medical need while enhancing our ability to achieve appropriate level of pricing, formulary access and reimbursement.

#### *Summary of Prior Clinical and Preclinical Studies*

##### *Clinical Studies*

#### *Clin301-201: A Randomized, Double-Blind, Placebo-Controlled, Sequential Parallel Study of CERC-301 in the Adjunctive Treatment of Subjects with Severe Depression and Recent Active Suicidal Ideation Despite Antidepressant Treatment*

Clin301-201 randomized 137 subjects to evaluate safety and efficacy of an 8 mg dose of CERC-301 for 28 days using a sequential parallel comparison design, or SPCD design. The primary endpoint of the study was to evaluate the antidepressant effect of CERC-301 after seven days of treatment assessed by the HAMD-17. Secondary endpoints were to evaluate the sustained antidepressant effect defined as the average between seven and 28 days of study drug treatment and the antidepressant effect of CERC-301 after 28 days of treatment assessed by the HAMD-17. In accordance with the SPCD experimental paradigm, subjects were randomized to one of three treatment sequences: 28 days of CERC-301 followed by seven days of placebo (12 mg loading dose on day 0 followed by 8 mg dose for 28 days), seven days of placebo followed by 28 days of CERC-301, or 35 days of placebo. While there was a slight numerical superiority for CERC-301 for the seven day primary endpoint, the results failed to reach statistical significance. There was no evidence for antidepressant effect at the 28 day endpoint, while numerical superiority for placebo was observed. There were no clinically meaningful or statistically significant changes in plasma BDNF levels with CERC-301 compared with placebo. There were no differences in mean blood pressure effects or heart rate between the treatment groups. We believe the lack of significant changes in plasma BDNF levels and blood pressure effects suggest drug exposure was inadequate in this study and that higher exposures should be explored in future studies. Additionally, we believe that refining our patient selection and changing our primary efficacy endpoint will improve the probability of producing positive future study results.

In general, CERC-301 was well tolerated with rates of adverse events similar to that of placebo. The most common treatment emergent adverse events were nervous system disorders, occurring in 25.9% and 26.9%, respectively, of subjects in the two active treatment sequences compared to 22.4% of subjects who received placebo during the entire study. Of the nervous system treatment emergent adverse events, dizziness was most common, occurring in 18.5% and 7.7%, respectively, of subjects in the two active treatment sequences compared to 2.0% of subjects who received placebo during the

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entire study. There was no difference in mean blood pressure effects in active groups compared to the placebo group. There was no detectable pattern of blood pressure increase either at pre-dose clinic measurements or transiently after dosing. Four serious adverse events in three subjects were reported during the conduct of the study, two in a subject randomized to placebo (suicide attempt; alcoholism) and two in subjects that received CERC-301 (worsening depression with psychotic features and unstable angina).

### *Clin301-200-A: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Two-Part Safety, Pharmacokinetic, and Pharmacodynamic Study of CERC-301 in Healthy Subjects*

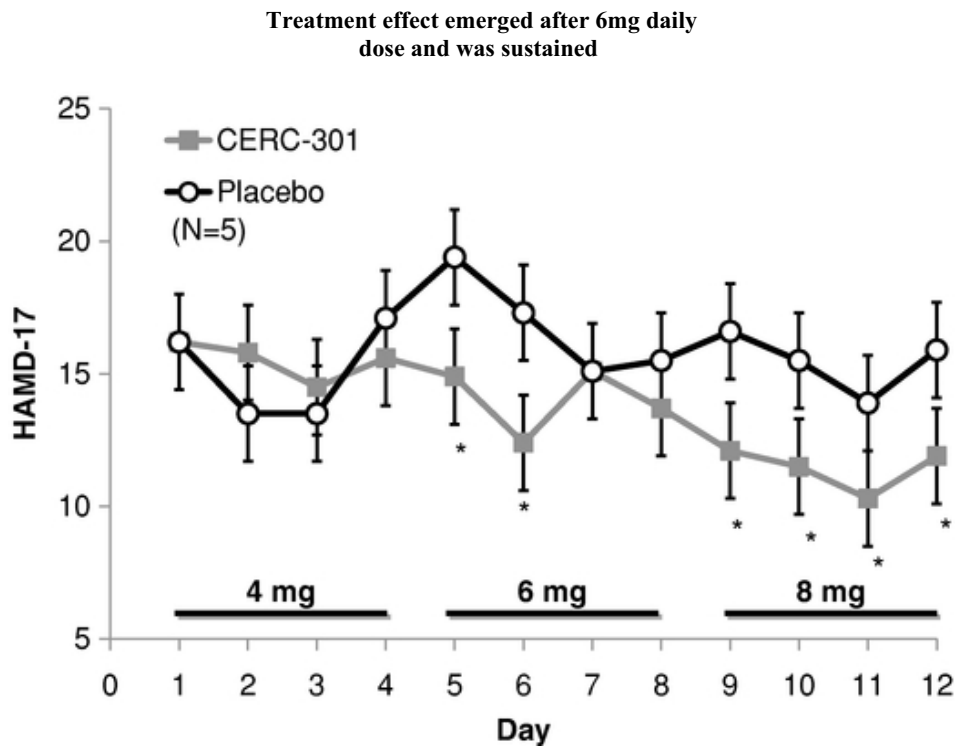
In the fourth quarter of 2014 we completed a 48-subject, three-part, seven day, inpatient exploratory study of CERC-301. The study investigated the dose-response relationship between CERC-301 and pharmacodynamic effects on blood pressure and BDNF in healthy subjects, including young, intermediate and elderly cohorts, and provided the repeat dose response data needed to support studies of CERC-301 at possibly higher doses and in larger, more diverse subject populations. Doses of 8 mg to 20 mg were administered in an inpatient setting to better understand the relationship among dose, plasma concentrations and adverse event profile, and to assess potential effects of subject age and gender. The study demonstrated near linear PK profile for CERC-301 with doses up to 20 mg daily in fed-state subjects being well tolerated. Some of the most commonly reported adverse events across the young dose groups were headache, feeling of relaxation, feeling abnormal, elevated mood, dizziness, increased energy, longorrhea, sedation, abnormal vision and palpitations. Overall, there were no clear-cut dose-related or age-related differences in adverse events. Relative to placebo, subjects who received CERC-301 demonstrated an increase in blood pressure, as measured by ambulatory blood pressure measurements, at all dose levels and experienced a trend of increased average 7-day BDNF levels at 16 mg and 20 mg. Blood pressure appeared to have the biggest change in the first four days of dosing for all doses, except for the 20 mg dose, which increased further from Day 4 to Day 7, consistent with CERC-301 exposure profile, which reaches steady state values by day five or six of dosing. Relative to placebo, the mean awake time ambulatory systolic blood pressure changes were £ 8 mm Hg on average across all doses on days one, four and seven, except in the 20 mg group, where on average there was a 9-15 mm Hg elevation in systolic blood pressure. There was no apparent age effect on blood pressure elevations across the three age groups and this study demonstrated no clear difference between genders across various cohorts. Ambulatory blood pressure measurements demonstrated that the maximum change generally occurred between two and three hours post-dose, consistent with CERC-301 peak plasma exposure in fed-state. We believe that these blood pressure results will be transient in our CLIN301-203 study as a result of the revised dosing schedule.

### *Human Proof of Concept Study in Treatment Resistant Depression*

The 2012 NIMH Study was a single center, randomized, double-blind, placebo-controlled crossover study of five subjects with TRD to evaluate the potential antidepressant efficacy and tolerability of CERC-301. It was conducted at the Clinical Research Center of the NIMH-NIH, where subjects were hospitalized for the duration of the study. Male and female subjects of the NIMH, ages 18 to 55 years, were recruited to participate; all subjects were diagnosed with MDD and were currently depressed without psychotic features. Subjects were required to have a score of 22 or higher on the Montgomery-Asberg Depression Rating Scale, or MADRS, at screening and at baseline, the day of first dose of study medication. In addition, subjects had to have previously failed at least two adequate antidepressant trials in the current depressive episode. Exclusion criteria included, but was not limited to, a recent history of drug abuse, diagnosis of bipolar disorder, psychotic features, suicidal ideation, serious unstable medical disorder or condition, previous use of ketamine or phencyclidine, and concomitant treatment with psychotropic medications in the two weeks before the study or electroconvulsive therapy in the three months before the study.

Following a one week drug-free period, five subjects were randomized in a double-blind manner to receive either CERC-301 or placebo for 12 days. Initial doses were 4 mg/day of CERC-301 for four days, then escalated to 6 mg/day for four days and then 8 mg/day for four days. The study's medication dose was increased in a blinded fashion every four days until completion of the treatment. At day 12, the study drug was discontinued; subjects remained drug-free for 14 days and then crossed over to the other treatment condition. Dosage in the second experimental treatment condition (days 27 through 38) was identical to the first crossover phase. By day nine, plasma BDNF levels were significantly higher in subjects receiving CERC-301 than in those receiving placebo, with  $p = 0.03$ . The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. Statistical significance of the trial results are typically based on widely used, conventional statistical methods that establishes the p-value of the results. A p-value of 0.05 or less is required to demonstrate statistical significance. As such, these BDNF levels are considered to be statistically significant.

CERC-301 demonstrated significant antidepressant effects as early as day five and nine compared to placebo, in two of the three standard scales used in assessing antidepressant response, the HAMD-17 ( $p=0.001$ ) and Beck Depression Inventory, or BDI ( $p = 0.01$ ) respectively. These two scales were two of the study's secondary endpoints. There were no significant adverse side effects observed, including changes in blood pressure. No improvement was noted with the third antidepressant scale, the MADRS, which was the primary efficacy parameter of the study. The following chart illustrates the results on the HAMD-17 antidepressant response scale:



*Additional Phase 1 Studies:* In 2004 through 2005, three Phase 1 clinical trials of CERC-301 in a total of 60 healthy volunteers receiving the study drug, were completed by Merck, each of which measured the safety and assessed the pharmacokinetics, or PK, of CERC-301. The first study, Study 001, measured single doses of the drug in a healthy, fasted and fed and young male population. The second study, Study 002, measured multiple doses in a healthy, fed and young male population. The final study, Study 003, measured single doses in healthy elderly male and female populations.



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CERC-301 was generally well tolerated, with the exception of dose-related increases in blood pressure, increases in orthostatic heart rate in three subjects, a mild decrease in blood pressure in one subject, and some adverse events of which central nervous system-related adverse effects were most common. Such adverse events were transient and mild to moderate in severity. No serious adverse effects were experienced in these studies. In subjects who received the highest dose of 20 mg while fasting, adverse events such as mild forgetfulness, dizziness, drowsiness, headache, lightheadedness, and difficulty concentrating were observed. Further, no clinically significant abnormalities were noted in respiratory rate, routine blood and urine chemistry panels, electrocardiogram tests, or physical examinations, including neurologic examinations.

Two additional Phase 1B studies were completed in subjects with moderate Parkinson's disease, for a total of 38 subjects, which did not show efficacy to control movement disorders. However, while some non-serious adverse events were found, contrary to what was observed in earlier studies, both studies, at single doses of 7 mg in the fed state, showed no clinically significant blood pressure elevations compared to placebo.

### *Preclinical Studies*

Preclinical studies conducted by Merck include the evaluation of safety pharmacology, PK and toxicology of CERC-301 in conscious animals, all of which have demonstrated a safety profile sufficient to enable ongoing and planned human clinical studies. The engagement of CERC-301 with brain NR2B, or target engagement, has also been demonstrated in rats, dogs, monkeys and in human cadaver tissue. The predicted blood exposure required to achieve target engagement has been described in these species. Live animal model studies have provided promising support for CERC-301's efficacy in treating Parkinson's disease related movement disorders, chronic pain and depression. In 2014, we conducted a Forced Swim Test, or FST, study that is a validated animal model of clinical MDD that demonstrates predictive validity for all known classes of effective antidepressants. Antidepressant-like activity is indicated by reductions in immobility. We tested doses of CERC-301 at 0.1, 0.3, 1, 3, 10, or 30 mg/kg and determined that CERC-301 exhibited antidepressant effects at the 1, 3, 10, and 30 mg/kg dose levels compared to the vehicle. Additional preclinical studies are ongoing.

### *Future Clinical Development*

Upon completion of Clin301-203, and dependent upon study results, we will conduct a multi-dose, six week Phase 2b study as adjunctive treatment in subjects with MDD who are currently experiencing a severe depressive episode despite stable ongoing treatment with a SSRI or SNRI. We expect to initiate this dose ranging study in the first half of 2017. Thereafter we plan to engage the FDA in an end-of-phase 2 meeting to align plans and activities for potential regulatory approval which would include Phase 3 clinical studies, non-clinical NDA enabling studies and manufacturing activities.

## **CERC-501**

### *Adjunctive Treatment of Major Depressive Disorder, Substance Use Disorders, & Treatment of Co-Occurring Disorders*

We intend to first develop CERC-501 for adjunctive treatment of MDD and for substance use disorders (e.g., nicotine, alcohol, and/or cocaine). If we receive approval for CERC-501 for adjunctive treatment of MDD and for substance use disorders, we plan to further develop CERC-501 for the concurrent treatment of MDD and substance use disorders, or co-occurring disorders.

### *Adjunctive Treatment of Major Depressive Disorder*

Depression is one of the most common serious medical and psychiatric disorders, with greater than 150 million adults worldwide suffering from MDD at any given time, according to a 2003 report by the World Health Organization, or WHO, titled *Investing In Mental Health*. According to the U.S. National Comorbidity Survey Replication published in 2007, or the NCS-R, more than 16 million adults in the United States, which represents approximately 6.7% of its entire adult population, will suffer from a MDD episode in a 12 month period. Furthermore, according to the NCS-R, approximately 45% of these cases can be classified as severe, and suicide is often a grave complication associated with depression. Studies have shown that approximately 50% to 70% of severely depressed patients have experienced suicidal ideation.

Numerous studies have shown that many patients do not respond to their initial antidepressant therapy. For example, according to a 2006 report titled *Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR-D Report*, or the STAR-D Report, 51.4% of patients failed to respond, defined as achieving a 50% reduction in symptoms, and only 36.8% became symptom free, or achieved remission, after their initial 12-week treatment course with monoamine antidepressants. As such, physicians commonly will switch patients' antidepressants to manage depression, and patients may require two or three courses of treatment, before achieving satisfactory relief. The depression may persist following a course of treatment and additional medications may need to be used adjunctively. These adjunctive agents may include atypical antipsychotics, like aripiprazole and quetiapine, or other agents such as bupropion and lithium. While certain patients experience improvement in their depressive symptoms when these additional therapies are added to their existing treatments, many do not. For example, according to a study published by Dr. Robert Berman and others in 2007, entitled *The Efficacy and Safety of Aripiprazole as Adjunctive Therapy in Major Depressive Disorder: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study*, only 32.4% of patients with treatment resistant depression responded to six weeks of adjunct treatment of the atypical antipsychotic aripiprazole.

### *Substance Use Disorders*

Drug abuse is a major public health problem that impacts society on multiple levels. According to *Results from the 2013 National Survey on Drug Use and Health*, a survey conducted by the Substance Abuse and Mental Health Services Administration, in 2013, an estimated 21.6 million persons in the United States aged 12 or older (8.2 percent) were classified with substance dependence or abuse in the past year based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition. Of these, 2.6 million were classified with dependence or abuse of both alcohol and illicit drugs, 4.3 million had dependence or abuse of illicit drugs but not alcohol, and 14.7 million had dependence or abuse of alcohol but not illicit drugs. Illicit drugs include marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants, or prescription-type psychotherapeutics (pain relievers, tranquilizers, stimulants, and sedatives) used nonmedically. Furthermore, in 2013, heavy drinking was reported by 6.3 percent of the population aged 12 or older, or 16.5 million people.

Cigarette smoking and exposure to tobacco smoke are the leading causes of preventable disease and death in the United States, resulting in more than 480,000 premature deaths and \$289 billion in direct health care expenditures and productivity losses each year. In 2013, 55.8 million persons (21.3 percent of the population) were current cigarette smokers. Despite progress over the past several decades, millions of adults still smoke cigarettes, the most commonly used tobacco product in the United States, and this continues to be major public health problem.

### *Co-Occurring Disorders*

Without considering nicotine dependence, there are more than 5 million adults in the United States alone who suffer from co-occurring depression and substance use disorders. Such comorbidities

put patients at greater risk. For instance, depending on when MDD onset occurs, MDD has been found to be related to the course of substance dependence, impacting areas such as remission of substance dependence and relapse into substance dependence after stable remission. Recent research suggests that a history of MDD is associated with a decreased ability to quit smoking and MDD over the last year is associated with an increased likelihood of smoking relapse. One common link between the co-occurrence of depression and substance use disorders may be stress. Sustained stressful experiences can induce despair and increase the risk of clinical depression and substance use. Stress and mood are significant components of addiction relapse as discussed in a 2000 article written by Watkins et al., titled *Neural Mechanisms Underlying Nicotine Addiction: Acute Positive Reinforcement and Withdrawal* published by the Journal of Nicotine & Tobacco Research. Substance use often provides relief from stress, such that the substance of abuse often becomes a potent behavioral reinforcer. Present pharmacologic treatments for co-occurring disorders consist either of treatment for the psychiatric disorder or the treatment for the addiction, but not the treatment of the underlying connection between the two. For example, the nonselective opioid antagonist naltrexone, an FDA-approved medication for alcohol dependence in patients who are able to abstain from alcohol in an out patient setting prior to treatment initiation, is not FDA approved as an antidepressant or an anti-anxiety agent. The smoking cessation aid varenicline, a mixed nicotinic agent, is associated with depression as a serious side effect. Similarly, antidepressant medication exerts a modest beneficial effect for patients with combined depressive and substance-use disorders. It is not a stand-alone treatment, and concurrent therapy directly targeting the addiction is also indicated, according to a 2004 review written by Nunes and Levin titled *Treatment of Depression in Patients with Alcohol or Other Drug Dependencies: A Meta-analysis*, published in the Journal of the American Medical Association (JAMA). Therefore, we believe a tremendous need exists for pharmacotherapies effective in the treatment of co-occurring disorders.

#### *Mood, Stress, Addiction and Kappa Opioid Receptors*

Kappa opioid receptors, or KORs, and their native ligand dynorphin are localized in areas of the brain which effect reward and stress and are believed to impact mood, stress and addictive disorders. As discussed in a paper by Shippenberg et al., titled *Dynorphin and the Pathophysiology of Drug Addiction* and published in the Journal of Pharmacology and Therapeutics in 2007, both KORs and dynorphin, together comprising the kappa opioid system, are upregulated by stress and chronic exposure to drugs of abuse, are thought to mediate the negative emotional states seen in drug withdrawal and contribute to stress-induced reinstatement of drug seeking behavior. In animal models it has been observed that stress produces a depressive state that is believed to be associated with the activation of KOR and subsequent downstream signaling events. Administration of agents that stimulate the KOR system, or KOR agonists that act like dynorphin, decrease dopamine levels in areas of the brain involved with executive function, produce anxiety-like and depression-like behaviors in animals, exacerbate behaviors associated with drug withdrawal and increase the reinforcing effects of substances of abuse.

#### *KOR Antagonism*

Much of the current knowledge of the kappa opioid system comes from studies of two prototypical KOR antagonists, nor-BNI and JDTic. In studies, such as those discussed by Lalanne et al. in a paper titled *The Kappa Opioid Receptor from Addiction to Depression and Back* and published in Frontiers in Psychiatry in 2014, KOR antagonists induced antidepressant-like effects in animal models and attenuate symptoms associated with withdrawal, such as anxiety behaviors. The therapeutic potential of KOR antagonism has been demonstrated in animal models of anhedonia, depression, and anxiety, and KOR antagonists reduce the signs of nicotine, heroin and alcohol withdrawal in rodent models of dependence. Based on the results of these studies, stress-induced reinstatement to drug seeking is blunted in mice who have their KOR system genetically deleted, and can also be blocked in wild-type

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mice by treatment with nor-BNI and rats treated with JD<sub>T</sub>ic. Based on the studies summarized by Lalanne et al., KOR antagonists reduce ethanol intake in a number of animal models. Overall, we believe the preclinical data to date support the emerging consensus that selective kappa opioid antagonists have antidepressant- and antianxiety- like effects, reduce addictive substance consumption, and reduce behaviors and signs of drug withdrawal. As these studies demonstrate efficacy in animal models of both mood and addictive disorders, we believe that these studies provide the basis for the use of KOR antagonists in mood and substance use disorders and have the potential to reduce comorbid mood disorders.

We believe that the rationale for CERC-501 as an adjunctive treatment of MDD is supported by the reported results for Alkermes' ALKS-5461, which is believed to be acting as a functional kappa antagonist. Alkermes has reported positive Phase 2 results for ALKS-5461 as an adjunctive antidepressant in MDD patients and has initiated a Phase 3 development program. According to a press release by Alkermes, "ALKS 5461 had an onset of effect, as measured by MADRS, evident after one week of treatment." This suggests a rapid response to antidepressant treatment but not as rapid as what has been reported in the ketamine depression clinical trials.

### *Our Solution*

In February 2015, we acquired rights to CERC-501, which was previously referred to as LY2456302 and OpRA Kappa, through an exclusive, worldwide, license from Eli Lilly and Company, or Lilly. CERC-501 is a high-binding, selective KOR antagonist. We believe that the availability of a highly selective, potentially well tolerated oral daily kappa antagonist like CERC-501 represents a unique drug development opportunity for substance use disorders, adjunctive treatment of MDD and potentially for co-occurring disorders. We believe CERC-501 may have the following advantages over conventional antidepressant and addiction therapies:

- highly specific and selective to KOR and, therefore, minimal off-target pharmacology;
- available in convenient, once-a-day oral dosing;
- rapid onset of action;
- potential efficacy against substance use disorders;
- potential efficacy against mood disorders; and
- potential ability to treat co-occurring disorders.

In the long term, we currently intend to target our development efforts at the treatment of co-occurring disorders, an under-served segment of patients. We believe competitively positioning CERC-501 as a treatment for substance use disorders, a once-a-day, oral adjunctive treatment of MDD, and, depending on marketing approval, a treatment for co-occurring disorders it has the potential to generate widespread market acceptance. We further believe that if CERC-501 has the ability to provide rapid onset of antidepressant effect, the market opportunity will be further expanded. As discussed below, we plan to leverage the external studies funded and conducted by third parties with our own internally funded clinical studies.

### *Our Program*

#### *Current Development Plan*

Our long term strategy is to develop CERC-501 as an adjunctive treatment of MDD, substance use disorders, and, depending on market approval, the treatment of co-occurring disorders. For approximately the next 24 months, we will evaluate the potential human utility of CERC-501 in smoking dependence, depression, cocaine dependence, and anhedonia and mood disorders based upon studies conducted by us and three studies conducted by third parties at academic centers, two of which are being conducted under the auspices of NIMH. We will be submitting the smoking study to the

FDA, which we refer to as Clin501-201 in the third quarter of 2015 and initiate the study in first half of 2016. In addition we are considering conducting a Phase 2 clinical study in inadequately treated subjects with MDD currently on antidepressants, with an initiation date in the second half of 2016.

*Study Clin501-201: A Randomized, Double-Blind, Placebo-Controlled, Crossover Design Study of CERC-501 in a Human Laboratory Model of Smoking Cessation.*

**Study Overview:** Clin501-201 is designed as a randomized, placebo-controlled double blind cross-over human laboratory study to evaluate the effects of 5 mg and 10 mg of CERC-501 on tobacco withdrawal and reinstatement and assess craving, mood and anxiety during 18 hours of abstinence in approximately 86 cigarette smokers who currently smoke at least 15 cigarettes per day. Clin501-201 uses a placebo and a crossover design with two periods. We believe that the cross-over design, by allowing for subjects to be their own control, significantly increases trial power as does the conduct of the study in a controlled laboratory environment.

**Study Design:** Clin501-201 consists of two periods. After the screening period of up to 21 days, subjects will be randomized in a 1:1 manner to one of two treatment regimens, 5 mg or placebo, or 10 mg or placebo. Each period consists of a seven day treatment period followed by a single testing day on Day 8. Subjects will participate in a laboratory session following the McKee Smoking Lapse Test and will be discharged from the clinic to undergo drug washout followed by the second period of the cross-over design. The McKee Smoking Lapse Test involves nicotine deprivation for 18 hours, beginning on the evening of the seventh day, and continuing to mid-day of the eighth day, followed by a delay period, 50 minutes in duration, and a self-administration period, 60 minutes in length, as described in more detail below. After screening, participants will be randomized to arm 1, consisting of placebo and 5 mg CERC-501, or arm 2, consisting of placebo and 10 mg CERC-501. Half of the participants in each arm will be randomized to receive placebo first and half will receive CERC-501 first.

The smoking lapse test involves assessment of tobacco craving, mood ratings and nicotine withdrawal after 18 hours of abstinence followed by the delay period where subjects are presented with a tray containing their preferred brand of cigarettes, a lighter, and an ashtray. Subjects will be instructed that they can begin smoking at any point over the next 50 minutes. However, for each five minute block of time a subject delays smoking, the subject will receive a financial reward. The time will be recorded when a subject announces that the subject wants to smoke. After their first cigarette or the completion of the delay period, a standardized scale known as the modified Cigarette Evaluation Questionnaire (mCEQ), will be administered to assess satisfaction, psychological reward, craving relief, enjoyment of airway sensations and other subjective effects associated with smoking. Upon smoking the first cigarette or completion of the delay period, the smoking self-administration period begins, and lasts 60 minutes. Subjects will be provided with eight cigarettes of their preferred brand. Money earned for delaying smoking will be paid to the subjects at the end of each laboratory session. The number of cigarettes smoked will be recorded. The primary endpoints for the study are the number of minutes (latency) to start of tobacco use during the delay period and the number of cigarettes smoked during the self-administration period.

Upon completion of the McKee Smoking Lapse Test, subjects will be discharged and begin a seven day washout period, although a three day window has been included to allow for subjects to remain in the study if they have an emergency or a planned vacation or other activity that would not allow them to make the exact visit date. Subjects will then return to the clinic to begin the second period of the cross-over design to receive placebo or active, with 5 mg or 10 mg, respectively, and repeat the above procedures and assessments. Upon discharge from the unit after the second period, subjects will be instructed to return for a final follow-up visit seven days later.

**Enrollment Strategies:** The study will be performed in volunteer subjects who are cigarette smokers currently not seeking treatment, who currently smoke at least 15 cigarettes per day, and smoke within five minutes of awakening every day. Recruitment is planned to be primarily through advertising.

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Subjects will be compensated for their participation in the study. The study will be performed at up to four sites that will contribute to enrollment. Strategies that we believe may maximize retention include dividing the screening procedures into two separate visits that allow the site to meet with subjects on unique occasions and gain an understanding of their reliability and commitment to the study before randomizing.

### *Overview of Externally Funded and Conducted Studies*

In connection with our in-license of CERC-501 from Lilly, we expect to receive the results upon the completion of three clinical trials that are enrolling subjects or will begin enrolling subjects by the end of the end of 2015. All of these studies are funded by grants from the NIMH or self-funded without any cost to us. The following is a summary of each of the three clinical trials:

- *Impact of the KOPr Antagonist OpRA Kappa in Persons at Specific Stages of Cocaine Addiction Trajectory, Versus Normal Volunteers.* This single site study, which began in September 2014, is being conducted under the leadership of Mary Jeanne Kreek, MD, Professor and Head of Laboratory, The Rockefeller University, and Senior Physician, The Rockefeller University Hospital.
- *Double-Blind, Placebo Controlled, Proof-of-Concept (POC) Trial of LY2456302, a Kappa Selective Opioid Receptor Antagonist, and Augmentation of Antidepressant Therapy in Treatment-Resistant Depression.* The primary investigator for this 5-site study, which has begun to recruit subjects, is Maurizio Fava, MD, Executive Director, MGH Clinical Trials Network and Institute and Executive Vice-Chair, Department of Psychiatry, Massachusetts General Hospital.
- *A Phase 2a Study to Evaluate the Kappa Opioid Receptor As a Target for the treatment of Mood and Anxiety Spectrum Disorders by Evaluation of Whether LY2456302 Engages Key Neural Circuitry Related to the Hedonic Response.* Dr. Andrew Krystal of Duke University Medical Center serves as the principle investigator of this 6 site study, which is expected to begin by the end of 2015.

Under clinical research agreements between Lilly and the third party research institutions conducting each of the clinical trials listed above, Lilly has the right to receive the results of each clinical trial. We are in the process of entering into tri-party agreements with Lilly and each third-party research institution so that we may be assigned the clinical research agreements. We have executed a tri-party agreement with Duke University and Lilly whereby we are assigned all of Lilly's rights and obligations under the clinical research agreement with Duke University. We are pursuing a similar agreement with MGH Clinical Trials Network and Institute and plan to propose a similar arrangement with The Rockefeller University Hospital.

In addition, there was a previously planned Phase 1 study of CERC-501 receptor occupancy to be conducted by Dr. Andrew Krystal of Duke University Medical Center and funded by NIMH. NIMH recently decided to discontinue the funding as it decided that the study would be unlikely to provide new information beyond what the above discussed NIMH funded Phase 2a study will provide. Depending on the results of Phase 2 studies for CERC-501, we may consider sponsoring this study or supporting the conduct of this study by a third party.

### Summary of Prior Preclinical and Clinical Studies

#### *Phase 1 Studies*

In 2008 through 2011, three Phase 1 clinical trials of CERC-501 in an aggregate of 82 healthy volunteers were completed by Lilly, each of which measured the safety and assessed the PK and PD of CERC-501. Study A was the first-in-human study of single escalating oral doses of CERC-501 administered to 32 healthy subjects and provided safety and PK data. The second study, Study B, assessed repeated daily doses of CERC-501 in 37 healthy subjects utilizing a dose range based on the results of Study A. Potential PK and cognitive interactions between CERC-501 and alcohol were also

investigated in Study B. Study C was conducted in 13 healthy male subjects to confirm the interaction of single oral doses of CERC-501 of between 0.5 mg to 25 mg with KORs in the brain, using positron emission tomography, or PET, imaging. The combined results of Studies A and C identified the doses at which CERC-501 provides KOR inhibition without mu opioid receptor, or MOR, inhibition, thus confirming the doses at which the drug remains KOR selective. The combined results from Study A and Study B suggested that CERC-501 was generally well tolerated by the healthy subjects administered up to 60 mg as a single dose, and up to 35 mg as multiple doses administered once daily for 14 days. One subject in Study B experienced a transient, clinically significant increase in ALT (liver transaminase) approximately two weeks after her last dose of 10mg of study drug. There were no serious adverse events observed in either study that were attributed to the study drug and no dose-limiting adverse events or other safety variables that were attributed to the study drug. The dose escalations in both studies were not limited by any safety findings. There were no clinically significant changes in neurohormones, including cortisol, prolactin, adrenocorticotrophic hormone, and luteinizing hormone in either studies, consistent with pre-clinical toxicology studies that revealed no evidence of hypothalamic or pituitary hormonal toxicities. The estimated PK parameters after single doses of CERC-501 were reasonably consistent across both studies. In Study B, CERC-501 had no effect on ethanol-induced cognitive/motor impairment.

In Study C, PET imaging was conducted and demonstrated that single oral doses of 0.5 mg to 25 mg of CERC-501 blocked KOR in the brain. KOR occupancy, or RO, was measured in high uptake regions of the brain, including amygdala, anterior cingulate, frontal cortex, and insula, at two time-points post-dose, approximately 2.5 hours post-dose and on the second day at around 22.5 hours post-dose. Consistent with preclinical studies, single oral doses of CERC-501 demonstrated rapid penetration and potent receptor occupancy in healthy human subjects, with 74% to 100% KOR occupancy at doses of 2 mg to 25 mg. Study C demonstrated that a single oral dose of 10 mg CERC-501 almost completely saturated kappa receptors at 2.5 hours post-dose, and that the lower range of RO at 22.5 hours post-dose exceeded 60%, supporting the clinical exploration of doses < 10 mg in future studies. Overall, clinical studies to date demonstrate that CERC-501 selectively blocks KOR without evidence of significant MOR antagonism within the dose range of 4 mg to 10 mg in humans, and the studies also suggest such dose levels may present a favorable safety profile. A limited number of the adverse effects observed in Studies A, B and C were considered by the investigators to be related to CERC-501. Additionally, there were no clinically significant changes in vital signs or electrocardiogram in the studies attributed to the study drug.

#### *Preclinical Studies*

Completed preclinical studies of CERC-501 include the evaluation of safety pharmacology, PK and toxicology of CERC-501 in conscious animals, all of which have demonstrated a safety profile sufficient at the intended dose to enable ongoing and planned human clinical studies. Our preclinical studies have revealed some limited safety findings, such as rat gastrointestinal issues, which we are further investigating. The engagement of CERC-501 with brain KORs, or target engagement, has also been demonstrated in rats and monkeys and the sufficient blood exposure required to achieve target engagement has been described in these species. To date, two preclinical studies in nicotine withdrawal, one in depression, and two in alcohol dependence have demonstrated efficacy, two of which are described below.

A standardized model of nicotine dependence involves infusion of nicotine via an attached pump into mice, discontinuation of the infusion is representative of spontaneous nicotine withdrawal. CERC-501, administered at doses ranging from 1 to 10 mg/kg reduced nicotine withdrawal behaviors in a dose-related manner, achieving statistical significance at 10 mg/kg. CERC-501 non-significantly decreased hyperalgesia at all doses tested and non-significantly decreased anxiety-like behavior in nicotine-withdrawn mice at 3 and 10 mg/kg. In a FST study, CERC-501 reduced swimming immobility,

a measure of depression-like behavior in a dose-dependent manner, with 10 mg/kg achieving efficacy comparable to the tricyclic antidepressant imipramine.

#### *Future Clinical Development*

Upon completion of Clin501-201, provided the results are indicative of potential efficacy and safety, we plan to conduct a dose ranging Phase 2b study in nicotine dependent smokers. In addition we are considering conducting a Phase 2 clinical study in inadequately treated subjects with major MDD currently on antidepressants. We will also monitor the results from the three externally funded and conducted future studies and based on the outcome of those clinical trials determine the merits of pursuing indications for adjunctive treatment of MDD, substance use disorders, and, depending on marketing approval, the treatment of co-occurring disorders. We also plan to engage the FDA in an end-of-Phase 2 meeting to align plans and activities for potential regulatory approval which would include Phase 3 clinical studies, non-clinical NDA enabling studies and manufacturing activities.

#### **COMTi Platform**

In March 2013, we acquired rights to our COMTi platform by means of an exclusive, worldwide license from Merck. COMT is an enzyme that is critical for the inactivation and metabolism of dopamine and its inhibition in the brain has demonstrated applicability in treating subjects with neuropsychiatric conditions, including MDD, schizophrenia, Parkinson's disease and pathological gambling. The COMTi platform includes access to a library of approximately 1,800 compounds that we believe increase dopamine levels in the prefrontal cortex, or PFC, which is the region of the brain that is responsible for working memory, attention tasks and decision making, all of which are human attributes that we collectively refer to as executive function. In January 2015, we selected CERC-406 as our first preclinical lead candidate from the COMTi platform. In 2015 and 2016, we intend to establish the data set necessary to select additional preclinical lead candidates and to initiate programs for treatment of various conditions where impaired executive function is a core symptom. These programs will target the improvement of working memory and executive function, which are key components of cognition.

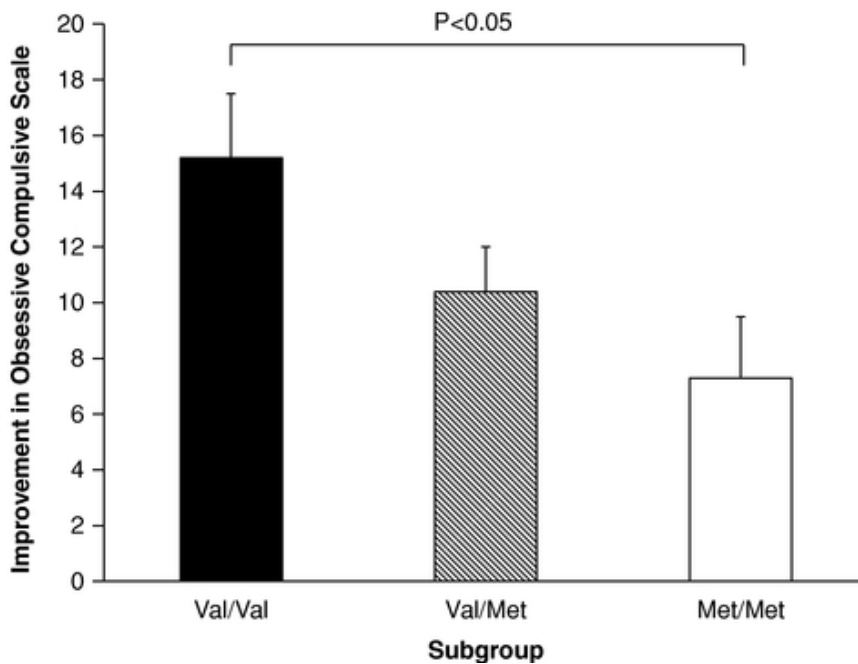
#### **COMT Overview**

We believe the neurotransmitter systems that are involved in executive function are targets for drug development, and include acetylcholine, serotonin, dopamine, glutamate and histamine. Most of these targets have a wide ranging impact on different brain functions or areas, and, as such, most drug development efforts are fraught with the lack of specificity of clinical effect of the drugs tested. On the other hand, higher-order cognitive functions, which impact areas such as thought, are governed by dopamine in the PFC. COMT is thought to break down dopamine and regulate dopamine levels in the PFC and we believe that brain COMT inhibition is a preferred target for treatment of cognitive impairment in conditions where loss of executive function is a key symptom. Specifically, COMT inhibition has demonstrated applicability in the significant improvement of aspects of executive function in persons suffering from schizophrenia, Parkinson's disease and pathological gambling.

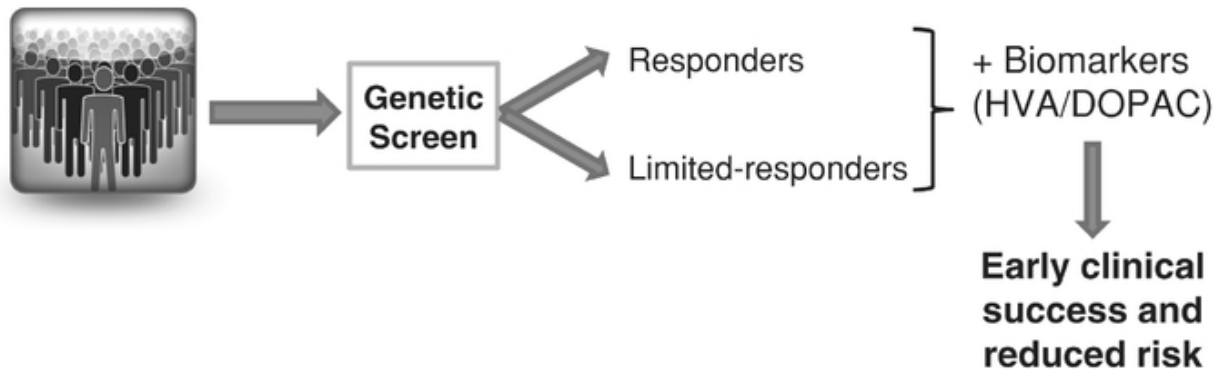
We believe brain COMT inhibition is a target with two key attributes that enable drug development—genetic variability and the availability of biomarkers. A genetic variation in the COMT enzyme, the Val allele, enhances the enzyme's baseline level activity and has been shown to be linked to reduced aspects of executive function in normal volunteers and in disorders associated with cognitive impairment. Research has suggested that the Val allele may be linked to reduced working memory and PFC physiological efficiency as assessed through brain imaging and increased response to a currently available COMT inhibitor, tolcapone. We believe these results suggest that COMT inhibition may improve PFC executive function in a genotype-specific and more predictable manner. This represents an opportunity to improve cognitive symptoms in patients with various diseases associated with executive dysfunction and who carry this genetic subtype. Support of this concept of stratification of



subjects by genotype, or pharmacogenomic approach, is found in a 2013 article titled *A Proof of Concept Study of Tolcapone for Pathological Gambling: Relationships with COMT Genotype and Brain Activation*, which demonstrated that this genotype is predictive of response to brain COMT inhibition. As indicated in the figure below, in this study of pathological gambling, the Val:Val subjects had a significantly improved response when compared to the Met/Met genotypes. By targeting this genotype, we believe we could see a significant improvement in magnitude and reliability of drug response.



The second attribute involves the use of biomarkers to monitor the level of enzyme inhibition by our novel COMT inhibitors. In cerebrospinal fluid, or CSF, the inhibition of COMT leads to an increase in the amounts of dihydroxyphenylacetic, or DOPAC, and a decrease in the amounts of homovanillic acid, or HVA. Samples of CSF are easily obtained in clinical studies via a spinal tap, or lumbar puncture, to measure concentrations of HVA and DOPAC. This allows for immediate measures of central dopamine breakdown. We plan to use these biomarkers in our first clinical trials in order to detect clinical efficacy in Phase 1. By exploiting this biomarker strategy and combining it with a pharmacogenomic approach, we are developing our novel COMT inhibitors as one of the first hypothesis-driven, biology-based, genotype-specific and targeted treatments of the impairment of executive function.



### ***Our COMTi Platform***

Our COMTi platform is comprised of a new generation of compounds with selectivity for membrane bound COMT, the dominant form of COMT found within the central nervous system. We believe these potent COMT inhibitors will selectively increase dopamine levels in the PFC, thereby improving executive function. Our development efforts are focused on a new generation of potent inhibitors that we believe avoid off-target toxicity and side effects seen with the previous generation of inhibitors, such as liver toxicity observed in tolcapone and diarrhea observed with entacapone and tolcapone. Our novel compounds are intended to have higher levels of penetration and selectivity for brain COMT, which we believe may lead to higher efficacy with lower administered doses. Our research indicates that our COMTi platform includes compounds with varying degrees of selectivity of peripheral versus brain COMT inhibition, including some that work on both peripheral and brain COMT, and some that work primarily on brain COMT. We believe this provides options for developing different compounds for different disease states. For example, we believe a COMTi for Parkinson's disease may need to provide both central and peripheral inhibition, in order to benefit both to the movement impairments of Parkinson's disease and the cognitive symptoms of the disease.

### **CERC-406**

#### *Residual Cognitive Symptoms in Major Depressive Disorder*

Depression is one of the most common serious medical and psychiatric disorders, with greater than 150 million adults worldwide suffering from MDD at any given time, according to the WHO report titled *Investing In Mental Health*. According to the NCS-R, more than 16 million adults in the United States, which represents approximately 6.7% of its entire adult population, will suffer from a MDD in a 12 month period. The WHO, in a report titled *Depression: A Global Crisis*, published on the occasion of World Mental Health Day, October 10, 2012, predicted that by 2020 MDD would be the second leading cause of disability worldwide.

Several publications including the 2014 article by Lam et al., titled *Cognitive Dysfunction in MDD: Effects on Psychosocial Functions and Implications for Treatment* published in the Canadian Journal of Psychiatry indicate that cognitive dysfunction is an important mediator of disability in MDD. Self-perceived cognitive impairment has always been recognized as a clinical manifestation of MDD. Cognitive domains that are measurably impaired in MDD include attention, memory, processing speed and executive function. As discussed by Lam et al., up to 50% of patients with MDD exhibit measureable cognitive deficits. Deficits in attention and executive function may persist even after remission. Cognitive dysfunction and functional impairments are two of the most common residual complaints among patients with MDD who achieve symptomatic remission. In a study of patients with MDD treated with antidepressants for at least three months who were considered to be in partial or complete remission, 30% to 50% reported residual cognitive symptoms that interfered with functioning. Thus, we believe cognitive dysfunction may represent a dimension of MDD that is independent of mood symptoms. Although standard antidepressants may improve cognitive deficits in MDD, we believe these effects may be limited in magnitude. Furthermore, as summarized in a 2009 article by Delgado and Schillerstrom titled *Cognitive Difficulties Associated with Depression* published in Psychiatric Times there is preliminary evidence indicating that cognitive deficits in MDD patients may predict the failure to respond to antidepressants. We believe there is a subgroup of patients exist who require additional treatment alternatives. According to Lam et.al, accumulating clinical evidence suggests that cognitive dysfunction is a core psychopathological feature of the disorder.

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Entacapone and tolcapone are two commercially available COMT inhibitors used to treat aspects of Parkinson's disease. Both drugs inhibit COMT outside of the nervous system, or peripheral COMT, and may be administered, with levodopa, which is the precursor to the neurotransmitter dopamine, multiple times per day. Tolcapone, which has modest brain penetration and inhibits brain COMT, is hampered by side effects including diarrhea and liver toxicity. Entacapone does not penetrate the brain. Because of these factors, neither drug is used clinically to treat executive function impairment. Nonetheless, pilot studies using tolcapone have repeatedly suggested an improvement in aspects of executive function in normal volunteers and in subjects with various conditions that are associated with cognitive impairment. Improvements in aspects of the underlying conditions were also found. In an open-label study published by Dr. Maurizio Fava and others in 1999 entitled *Open Study of the Catechol-O-Methyltransferase Inhibitor Tolcapone in Major Depressive Disorder*, tolcapone significantly improved core depressive symptomatology, including HAMD-17 scores, in a cohort of 21 adult subjects with MDD.

### *Our Solution*

CERC-406 is a small molecule, that research indicates is a selective COMT inhibitor with low inhibitory activity on peripheral COMT. We are currently planning to develop CERC-406 as a "first-in-class," oral adjunctive medication for patients with residual cognitive impairment symptoms suffering from MDD. We selected CERC-406 as our preclinical lead candidate from our COMTi platform because in preclinical testing it demonstrated lower potential of peripheral, off target side effects, rapid absorption and bioavailability, good brain penetration and a favorable dose-dependent biomarker profile in rats. CERC-406 has also demonstrated off-rate on brain COMT that is slower than tolcapone, implying a good duration of effect. Finally, CERC-406 has demonstrated a favorable safety profile in all studies conducted to date. In preliminary studies it appears that CERC-406 may have favorable drug distribution and metabolism properties, suggesting that it has the potential to be administered orally on a once or twice daily basis.

We believe that CERC-406 will:

- demonstrate efficacy as it is a brain penetrant COMT inhibitor with selectivity for MB-COMT to target the PFC dopamine deficit in this patient population;
- be more effective in Val homozygotes population, who have higher levels of COMT activity and lower prefrontal dopamine receptor activation; and
- be safer than existing COMT inhibitors—existing COMT inhibitors are not ideal as such inhibitors have adverse events such as liver toxicity and diarrhea.

### *Our Program*

We are planning to develop CERC-406 for the enhancement of executive function and working memory in MDD, where we believe a new therapy with efficacy in residual cognitive symptoms will be associated with improved functional outcomes. We may also perform early exploratory clinical studies in subjects with high unmet medical needs, such as individuals with depression, schizophrenia, impulse control disorders or Parkinson's disease. While COMT inhibition may eventually find broad use in multiple neurological and psychiatric diseases, we plan to focus on indications where high COMT activity is known to contribute to the disease process and where the Val:Val genotype has already been identified as a vulnerable population in the condition or disease state. We intend to measure the biomarkers of COMT activity and dopamine metabolism in genetically defined cohorts in our initial human studies, thus providing biological proof of concept and dose response data early in clinical development. By exploiting this biomarker strategy and combining it with a pharmacogenomic approach, we are developing our CERC-406 as one of the first hypothesis-driven, biology-based, genotype-specific and targeted treatments of the impairment of executive function.

### *Current Development Plan*

In 2015 and 2016, as part of our pre-IND efforts, we intend to advance the characterization of the safety and efficacy of CERC-406 in pre-clinical animal studies and to advance manufacturing of product for clinical trials. We plan to file an IND for CERC-406 in the first half of 2017. Upon acceptance of this IND filing, we will commence Phase 1 studies to examine human safety, tolerability and pharmacokinetics that will determine suitability for further development. Subsequently, other compounds can be brought into development to target other cognition-related disorders. Alternatively, CERC-406 could be carried forward to target other conditions.

### *Summary of Preclinical Studies*

Preclinical studies on CERC-406 to date have been focused towards demonstration of an acceptable safety, metabolic, and toxicity profile for CERC-406, deeming it qualified for further development and advancement into IND-enabling studies. Preclinical medicinal chemistry synthetic scale-ups, a series of studies related to absorption, distribution, metabolism, excretion, PK characterizations, safety screening for liver toxicity, and target validation with use of cerebrospinal fluid biomarker measurement in rats as proof of concept all have provided supporting data for advancement of CERC-406 towards IND-enabling studies.

### *Clinical Development Plan*

Upon acceptance of CERC-406's IND filing, we will commence Phase 1 studies to examine human safety, tolerability and pharmacokinetics that will determine suitability for further development. Current development with respect to CERC-406 allows us to measure the biomarkers of COMT activity in genetically defined cohorts in our initial human studies, thus providing biological proof of concept and dose response data early in clinical development.

### **Other Business Development Activities**

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including strategic partnerships, collaborations, joint ventures, business combinations and investments. We believe we have the ability to identify, evaluate and procure valuable product programs that are consistent with our goal of becoming a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. We plan to continue to leverage these opportunities to expand our product candidate portfolio in a fashion that fits within our core strategy and enhances our overall value.

### **Intellectual Property**

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, their methods of use, related technology and other inventions that are important to our business. As more fully described below, we have issued patents covering the compounds and compositions of CERC-301 and CERC-501. We have also filed multiple patent applications directed to COMT inhibitor compounds and methods of use. In 2014 and 2015, we received Notices of Allowance for two U.S. patent applications that broadly and/or specifically cover current compounds of interest within the COMTi Platform, including CERC-406. Both of the allowed U.S. applications issued as patents in 2015. We also may rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of central nervous system disorders.

The patent positions of biopharmaceutical companies are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office, or USPTO, or a foreign patent office to determine priority of invention or in post-grant challenge proceedings, such as oppositions, that challenge priority of invention or other features of patentability. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

The patent portfolios for our most advanced programs are summarized below.

- **CERC-301.** We possess worldwide exclusive rights to manufacture, use and sell certain NR2B antagonist compounds. The CERC-301 patent portfolio consists of three patent families. The first family consists of patents that have issued in the United States, Australia, Canada, Germany, France, Great Britain, Switzerland and Japan. The patents in the first family include composition of matter and use claims of varying scope, including picture claims to CERC-301 or a pharmaceutically acceptable salt thereof. The expiration date of the U.S. patent in the first family is August 31, 2026, not including any patent term extension or market exclusivity period which may apply. The second family consists of patents that have issued in the United States, Germany, France and Great Britain. The patents in the second family include composition of matter claims (in U.S. patent only) and use claims that generically cover CERC-301. The expiration date of the U.S. patent is June 3, 2022, not including any potential patent term extension or market exclusivity period. The third family consists of a U.S. provisional patent application which includes claims to compositions of matter, methods of use, and methods of manufacture. U.S. nonprovisional and international patent applications that claim priority to the provisional application are expected to be filed by December 2015. Any patent issuing from any such U.S. nonprovisional application is predicted to expire in 2035 at the earliest, not including any potential patent term extension or market exclusivity period.
- **CERC-501.** We possess worldwide exclusive rights to manufacture, use and sell certain KOR antagonist compounds. The CERC-501 patent portfolio consists of a single patent family with dozens of issued patents and pending patent applications, including patents issued in the U.S., Australia, Canada, China, Europe and Japan. The patents in this family include composition of matter claims, including picture claims to CERC-501 or a pharmaceutically acceptable salt thereof, and/or use claims of varying scope. The expiration date of the two U.S. patents is January 13, 2029, not including any potential patent term extension or market exclusivity period.

- **CERC-406 and COMTi Platform.** We possess worldwide exclusive rights to manufacture, use and sell COMT inhibitor compounds. The COMT patent portfolio includes three patent families. Each patent family consists of patent applications filed in the United States, Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, Mexico and Russia. Any patents issuing from these patent applications are predicted to expire at the earliest in 2031, not including any potential patent term extension or market exclusivity period. In 2014 and 2015, we received Notices of Allowance for two U.S. patent applications that broadly and/or specifically cover current compounds of interest within the COMTi Platform, including CERC-406. Both of the allowed U.S. applications issued as patents in 2015.
- **FP01.** On March 17, 2015, we provided notice to Johns Hopkins University that we were terminating the exclusive, worldwide license to develop and market FP01 in chronic, persistent cough. Such termination will be effective on June 15, 2015 and, thereafter, we will no longer have any rights to the previously-licensed intellectual property concerning FP01.

The term of any individual patent depends upon the legal term of the patents in the countries in which they are obtained. In most countries where we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the patent term of a patent that covers an FDA-approved drug that contains an active ingredient or salt or ester of the active ingredient that has not previously been marketed may also be eligible for patent term extension, which permits patent term restoration to account for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is based upon one half of the time between the IND effective date and a company's initial submission of a marketing application, plus the entire time between the submission of the marketing application and the FDA's approval of the application. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

For all of our product candidates, we intend to explore at each stage of the drug discovery process opportunities for follow-on patent filings to maximize patent terms and market exclusivities. Such follow-on patent filings may be directed to new indications, formulations, combination therapies, manufacturing methods, dosages, routes of administration, patient populations, contraindications, drug interactions (or absence of interactions) or other aspects of drug labels.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and

development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

## **Manufacturing and Clinical Research**

We do not have any manufacturing facilities or personnel. We rely on contract manufacturing organizations, or CMOs, to produce our drug candidates in accordance with applicable provisions of the FDA's current Good Manufacturing Practice, or GMP, regulations for use in our clinical studies. The manufacture of pharmaceuticals is subject to extensive GMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

### *CERC-301*

We currently purchase the active ingredient of CERC-301 tablets, which is available from multiple sources, from one supplier. Xcelience currently manufactures the drug product for clinical testing. We intend to identify and qualify multiple manufacturers to provide the active pharmaceutical ingredient, drug product and fill-and-finish services prior to submission of a new drug application to the FDA. In preparation for Clin301-203, we expect to enter into multiple contract service agreements with providers of administrative, data capture, management, monitoring and statistical analysis services relating to our Clin301-203 study. We will remain substantially responsible for overseeing and managing the conduct of the Clin301-203 study in the U.S., with separate agreements with investigative sites performing the study, other clinical research organizations and other third-party vendors.

### *CERC-501*

As part of the exclusive license agreement with Lilly, we assumed all accountability and responsibility for existing drug substance, drug product and packaged clinical trial material of CERC-501, as well as all future manufacturing of CERC-501 for development and commercialization. Currently, clinical trial material necessary for supplying the existing studies for CERC-501 are warehoused with one supplier. Almac Group is a provider of a comprehensive range of services extending from research through pharmaceutical and clinical development to commercialization of product. We intend to identify and qualify multiple manufacturers to provide the active pharmaceutical ingredient, drug product and fill-and-finish services prior to submission of a new drug application to the FDA.

In preparation for Clin501-201, we expect to enter into a master contract services agreement with Vince and Associates Clinical Research, or Vince, under which Vince will provide administrative, data capture, management, monitoring and statistical analysis services relating to our Clin501-201 study. We expect that Vince will be substantially responsible for overseeing and managing the conduct of the Clin501-201 study in the U.S., although we will remain ultimately responsible for the study and will have separate agreements with investigative sites performing the study, other clinical research organizations and other third-party vendors.

All of our drug candidates are small compounds and are manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry is amenable to scale up and does not require unusual equipment in the manufacturing process. We expect to continue to develop drug candidates that can be produced cost-effectively at contract manufacturing facilities.

## **License Agreements**

### *Merck CERC-301 License*

In March 2013, we entered into an exclusive license agreement with Merck pursuant to which Merck granted us rights relating to certain small molecule compounds which are known to inhibit or

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antagonize the activity of the NR2B receptor as its primary mechanism of action and any pharmaceutical product containing such compounds, or an NR2B Product, for the prevention, diagnosis and/or treatment of all disease in humans. Merck retained a co-exclusive right to conduct non-human and non-clinical research under patents for the licensed NR2B antagonist compounds and NR2B Products. In addition to the license grant, Merck agreed that for a period of three years from the effective date of the license agreement that it would not, either by itself or through collaboration with a third party, develop, manufacture or commercialize anywhere any product comprising an NR2B antagonist compound.

In connection with the license grant of certain NR2B antagonist compounds and NR2B Products, we granted Merck a right of first negotiation to obtain an exclusive, worldwide license and/or other worldwide rights to research, develop, commercialize, sell and/or offer for sale any such NR2B Product. Pursuant to such right of first negotiation, we must provide advance notice to Merck if we intend to offer a license of any kind, or to assign or transfer or otherwise convey any other rights related to the development or commercialization of an NR2B Product. If Merck either chooses not to exercise its right of first negotiation or we fail to enter into an agreement with Merck as provided in the agreement, we will be free to enter into negotiations and contract with third parties with respect to such NR2B Product and will have no further obligation to Merck regarding such NR2B Product. In November 2013, we provided notice to Merck of our intent to potentially license or transfer CERC-301 and, after evaluating, Merck ultimately decided not to exercise its right of first negotiation with respect to CEC-301. As a result, pursuant to the terms of the license agreement, Merck no longer has, and we no longer have an obligation to provide, a right of first negotiation to Merck with respect to CERC-301.

In consideration of the license, we are required to make an initial aggregate payment of \$1.5 million. We made an initial payment of \$750,000 pursuant to the terms of the license within 45 days of the execution of the license agreement. The balance of the initial payment is due upon the later of (i) FDA acceptance of Merck preclinical data and (ii) FDA acceptance of data from a study that results in the FDA approving a Phase 3 clinical trial for an NR2B Product candidate. For each NR2B Product we develop, we are required to make milestone payments in an amount not to exceed, in the aggregate, \$40.5 million upon the achievement of various development and regulatory milestones, including first commercial sale. Additionally, we are required to make sales milestone payments in an amount not to exceed \$15.0 million. Upon commercialization of an NR2B Product, we will pay Merck a royalty in the high single digits on net sales of NR2B Product. The royalty obligation will be on a product-by-product and country-by-country basis until the later of (i) the expiration of the last to expire valid patent claim of a patent licensed to us under the license agreement covering the NR2B Product in such country, and (ii) ten years from the first commercial sale of the NR2B Product in such country.

Our license agreement with Merck will remain in effect on a product-by-product and country-by-country basis until our obligation to pay royalties under the license agreement expire with respect to such product in such country. Upon expiration of the license agreement with respect to a product in a country, our license grant for such product in such country will become a fully paid-up, royalty-free, irrevocable, perpetual non-exclusive license.

We have the unilateral right to terminate the license agreement in its entirety without cause upon 90 days prior written notice to Merck. Either party may terminate the license agreement in its entirety in the event of an uncured material breach by the other party, upon the other party's filing or institution of bankruptcy, reorganization, liquidation or receivership proceeding or upon an assignment of a substantial portion of its assets for the benefit of creditors. Merck may terminate the license agreement with respect to a particular patent licensed to us if we challenge the validity or enforceability of such patent. If Merck terminates the agreement for cause, or if we exercise our right to terminate the agreement without cause, the rights granted to us under this license will revert to Merck.



***Lilly CERC-501 License***

In February 2015, we entered into an exclusive license agreement with Lilly pursuant to which Lilly granted us rights relating to certain small molecule compounds which are potent and selective kappa opioid receptor, or KOR, antagonists and any pharmaceutical product containing such compounds, or a KOR Product, for the prevention, diagnosis and/or treatment of all disease in humans. In connection with the license grant of certain KOR antagonist compounds and KOR Products, we granted Lilly a right of first negotiation to obtain an exclusive, worldwide license and/or other worldwide rights to develop or commercialize any such KOR Product. Pursuant to such right of first negotiation, we must provide advance notice to Lilly if we intend to offer a license of any kind, or to assign or transfer or otherwise convey any other rights related to the development or commercialization of a KOR Product. If Lilly either chooses not to exercise its right of first negotiation or we fail to enter into an agreement with Lilly as provided in the agreement, we will be free to enter into negotiations and contract with third parties with respect to such KOR Product and will have no further obligation to Lilly regarding such KOR Product.

In consideration of the license, we are required to make an initial aggregate payment of \$1.0 million. We made an initial payment of \$750,000 pursuant to the terms of the license within 30 days of the execution of the license agreement. The balance of the initial payment is due 30 days after completion of the final study report for the 9-month toxicology study to be conducted by us in non-human primates. For the first KOR Product we develop, we are required to make milestone payments in an amount not to exceed, in the aggregate, \$19.0 million upon the achievement of various development and regulatory milestones, including first commercial sale. Additionally, we are required to make sales milestone payments in an amount not to exceed \$30.0 million. Upon commercialization of a KOR Product, we will pay Lilly a tiered royalty on net sales of KOR Product from mid-single digits to low-double digits. The royalty obligation will be on a product by product and country by country basis until the later of (i) the expiration of the last to expire valid patent claim of a patent licensed to us under the license agreement covering the KOR Product in such country, and (ii) eleven years from the first commercial sale of the KOR Product in such country.

Our license agreement with Lilly will remain in effect on a product by product and country by country basis until our obligation to pay royalties under the license agreement expire with respect to such product in such country. Upon expiration of the license agreement with respect to a product in a country, our license grant for such product in such country will become a fully paid up, royalty free, irrevocable, perpetual non exclusive license.

We have the unilateral right to terminate the license agreement in its entirety without cause upon 90 days prior written notice to Lilly. Either party may terminate the license agreement in its entirety in the event of an uncured material breach by the other party, upon the other party's filing or institution of bankruptcy, reorganization, liquidation or receivership proceeding or upon an assignment of a substantial portion of its assets for the benefit of creditors. If Lilly terminates the agreement for cause, or if we exercise our right to terminate the agreement without cause, the rights granted to us under this license will revert to Lilly.

***Merck COMTi License***

In March 2013, we entered into an exclusive license agreement Merck pursuant to which Merck granted to us certain rights in small molecule compounds which are known to inhibit the activity of COMT as its primary mechanism of action and any pharmaceutical product containing such compounds, or a COMTi Product, in each case for the prevention, diagnosis and/or treatment of all disease in humans. Merck retained a co-exclusive right to conduct non-human and non-clinical research under such patents for certain COMT compounds.

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In addition to the agreed-upon COMT compounds that are licensed to us, we have the right to request that up to 60 additional COMT compounds be included in our license grant during the two year period after we entered into the license agreement with Merck. Merck may only reject the inclusion of such COMT compound if such COMT compounds meet certain criteria that we have agreed to with Merck in the license agreement. Otherwise, such COMT compounds will be included in our license grant.

In connection with the license grant of certain COMT compounds and COMT Products, we granted Merck a right of first negotiation to obtain an exclusive, worldwide license and/or other worldwide rights to research, develop, commercialize, sell and/or offer for sale any such COMT Product. Pursuant to such right of first negotiation, we must provide advance notice to Merck if we intend to offer a license of any kind or to assign or transfer or otherwise convey any other rights related to the development or commercialization of a COMT Product. If Merck either chooses not to exercise its right of first negotiation or we fail to enter into an agreement with Merck as provided in the agreement, we will be free to enter into negotiations and contract with respect to such COMT Product with a third party and will have no further obligation to Merck regarding such COMT Product.

In consideration of the license, we made a \$200,000 upfront payment to Merck. For each COMT Product we develop, we are required to pay up to \$6.15 million in milestone payments upon achievement of various development and regulatory milestones. Upon commercialization of a COMT Product, we are required to pay Merck a royalty of a low single digit on net sales of a COMT Product. The royalty obligation will be on a product-by-product and country-by-country basis until the later of (a) the expiration of the last to expire valid patent claim of a patent licensed to us under the license agreement covering the COMT Product in such country, and (b) ten years from the first commercial sale of the COMT Product in such country.

Our license agreement with Merck will remain in effect on a product-by-product and country-by-country basis until our obligation to pay royalties under the license agreement expire with respect to such product in such country. Upon expiration of the license agreement with respect to a product in a country, our license grant for such product in such country will become a fully paid-up, royalty-free, irrevocable, perpetual non-exclusive license.

We have the unilateral right to terminate the license agreement in its entirety without cause upon 90 days prior written notice to Merck. Either party may terminate the license agreement in its entirety in the event of an uncured material breach by the other party, upon the other party's filing or institution of bankruptcy, reorganization, liquidation or receivership proceeding or upon an assignment of a substantial portion of its assets for the benefit of creditors. Merck may terminate the license agreement with respect to a particular patent licensed to us if we challenge the validity or enforceability of such patent. If Merck terminates the agreement for cause, or if we exercise our right to terminate the agreement without cause, the rights granted to us under this license will revert to Merck.

### **Commercialization**

We have not yet established a sales, marketing or product distribution infrastructure because our candidates are still in preclinical or early clinical development. We intend to selectively retain commercialization or co-commercialization rights in the United States for CERC-301, CERC-501 and certain indications of our COMTi platform, which we may complement with co-promotion agreements with partners. For those product candidates for which we receive marketing approval, we plan to build a specialty sales force and marketing team as well as to collaborate with third parties to market the approved product candidates in the United States. We may also seek to commercialize any of our approved products outside of the United States, although we only plan to do so with one or more collaborators.

## Competition

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target. Even if we and our potential collaborators are successful in developing our product candidates, the resulting products would compete with a variety of established drugs in the areas of depression, bipolar depression, post-partum depression, schizophrenia, Parkinson's disease and impulse control disorders, or ICDs.

### *CERC-301:*

Our lead product candidate, CERC-301, will compete with other drugs used as adjunctive therapies for the treatment of MDD, such as Abilify, marketed by Otsuka America Pharmaceutical, Inc. and Bristol-Myers Squibb; Seroquel XR, marketed by Astra Zeneca; and bupropion, a generic drug. Furthermore, to our knowledge, there are five competitive rapid onset antidepressant or anti-suicide programs in development:

- Esketamine is in Phase 3 development by Johnson & Johnson, or J&J, for administration as a nasal spray;
- AZD8108 is in Phase 1 development by AstraZeneca Pharmaceuticals LP, for oral administration;
- Rapastinel is approaching Phase 3 development by Naurex Inc., or Naurex, which has recently entered into an agreement to be acquired by Allergan plc, or Allergan for intravenous administration;
- NRX 1074 by Naurex (which has recently entered into an agreement to be acquired by Allergan) has completed a single intravenously administered dose Phase 2 study, which, along with oral and intravenous Phase 1 PK findings, will be used to select an oral dose for a repeat-dose Phase 2 study; and
- ALKS-5461, which is believed to be acting as a functional kappa antagonist, is in Phase 3 development by Alkermes plc, or Alkermes, as an oral application and has shown signals of rapid onset as an adjunctive therapy.

### *CERC-501:*

There are no approved pharmacologic treatments for co-occurring disorders even though there are likely more than 5.0 million Americans alone who suffer from co-occurring depression and substance use disorders. Our second Phase 2 product candidate, CERC-501, is being developed with the ultimate goal of treating such co-occurring disorders. To our knowledge, there are no other single moiety selective KOR antagonists in development to date. ALKS 5461, however, is believed to be acting as a functional KOR antagonist that is now in Phase 3 development for MDD as an adjunctive antidepressant in patients with MDD who have no more than two inadequate responses to antidepressant therapy. To our knowledge, the only other competitive program that is being studied in depression and substance use disorders is LY2940094 by Lilly that is in Phase 2 development for the treatment of both MDD and alcohol dependence.

### *COMT Inhibitor Platform*

Our potential products for the treatment of schizophrenia would compete with Zyprexa, marketed by Lilly; Risperdal, marketed by J&J; Abilify, Seroquel, and Clozaril. Zyprexa (olanzapine), Risperdal

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(risperidone), Seroquel (quetiapine) and Clozaril (clozapine) are all now generic in the United States. Currently, no treatments are approved for cognitive impairment associated with schizophrenia, although Forum is developing EVP-6124 (encenicline) which is in Phase 3 development by for the treatment of cognitive impairment in schizophrenia.

Our potential products for the treatment of the cognitive impairment of Parkinson's disease may compete with existing COMT inhibitors Comtan (entacapone), marketed by Novartis Pharmaceuticals Corp., or Novartis, (licensed from Orion), Tasmar (tolcapone), marketed by Valeant, and Stalevo (fixed combinations of entacapone and levodopa/carbidopa), also marketed by Novartis (licensed from Orion). Comtan, Tasmar, and Stalevo are all generic in the United States. Currently, no treatments are approved for cognitive impairment in Parkinson's disease.

Our potential products for the treatment of ICDs would compete with the off-label use of SSRIs. In addition, the pure opioid antagonist, Revia (naltrexone) is approved for treating alcohol dependence and the blockage of the effects of exogenously administered opioids and is marketed by Teva Women's. The FDA has not approved specific medications in the treatment of ICDs; however, some medications have proven effective, including SSRI antidepressants.

### *CERC-406:*

There are no approved pharmacologic treatments for cognitive impairment associated with MDD in the U.S. at this time. In March 2015, vortioxetine (Brintellix®), marketed in the United States by Lundbeck Pharmaceuticals, which was originally developed and commercialized for the treatment of MDD, received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency to expand the label to include information for cognitive function in patients with depression. A supplemental application for the addition of clinical data to the FDA approved product label for Brintellix was recently accepted by the FDA for review.

In addition, the companies described above and other competitors may have a variety of drugs in development or may be awaiting FDA approval that could reach the market and become established before we have a product to sell. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small compound drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory clearances.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

- capital resources;
- research and development resources;
- manufacturing capabilities; and
- sales and marketing.

Smaller companies may also prove to be significant competitors, particularly through proprietary research discoveries and collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific and management personnel and for licenses to additional technologies. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, and more affordable or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Developments by others may render our product candidates or our technologies obsolete. Our failure to compete effectively could have a material adverse effect on our business.

## **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, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export, pricing, and government contracting related to pharmaceutical products such as those we are developing. The processes for obtaining marketing approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

### ***United States 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 marketing 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 United States 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, or other actions, such as the FDA's delay in review of or refusal to approve a pending NDA, withdrawal of an approval, imposition of a clinical hold or study termination, issuance of Warning Letters or Untitled Letters, mandated modifications to promotional materials or issuance of corrective information, requests for product recalls, consent decrees, corporate integrity agreements, deferred prosecution agreements, product seizures or detentions, refusal to allow product import or export, total or partial suspension of or restriction of or imposition of other requirements relating to production or distribution, injunctions, fines, debarment from government contracts and refusal of future orders under existing contracts, exclusion from participation in federal and state healthcare programs, FDA debarment, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment.

The process required by the FDA before a new 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;
- approval by local or central independent institutional review boards, or IRB, before each clinical trial may be initiated;

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- performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with good clinical practices, or GCP, and regulations 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 GMP, regulations and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance; and
- FDA review and approval of the NDA.

Additionally, if a drug is considered a controlled substance, prior to the commencement of marketing, the DEA must also determine the controlled substance schedule, taking into account the recommendation of the FDA.

### *Preclinical Studies and IND Submission*

Preclinical studies include laboratory evaluation of product chemistry, pharmacology, 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. Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, among other things, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk. The FDA may raise concerns or questions related to one or more proposed clinical trials and place 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.

### *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, and review and approval by an IRB. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, a central IRB or local 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, and the IRB must continue to oversee the clinical trial, including any changes, while it is being conducted. Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or subjects 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. In Phase 2, the drug typically is administered through well-controlled studies to a limited subject population with the target disease or

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condition 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. In Phase 3, the drug is administered to an expanded subject population, generally at geographically dispersed clinical trial sites, in two adequate and 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.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to GMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as United States export requirements under the FDCA.

Progress reports and other summary information detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if certain serious adverse events occur or other significant safety information is found. 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 or the trial is not being conducted in accordance with the applicable regulatory requirements or the protocol. 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 subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

### *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. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. A waiver from the application user fee may be sought by an applicant. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first human drug application. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application. The FDA aims to review 90% of all standard review applications within ten months of acceptance for filing and six months of acceptance for filing for priority review applications.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration 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.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, either during the application process or after the approval of the drug to ensure the benefits of the drug outweigh the risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and 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.

Under the FDCA, before approving a drug for which no active ingredient (including any ester or salt of active ingredients) has previously been approved by the FDA, the FDA must either refer that drug to an external advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the drug to an advisory committee. The external advisory committee review may also be required for other drugs because of certain other issues, including clinical trial design, safety and effectiveness, and public health questions. 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 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 GMP requirements and adequate to assure consistent production of the product within required specifications by the manufacturer and all of its subcontractors and contract manufacturers. Additionally, before approving an NDA, the FDA will inspect one or more clinical trial sites to assure compliance with GCP regulations.

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 marketing approval. The FDA may not grant approval of an NDA 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, or other information, in order for FDA to reconsider the application. The FDA has a review goal of completing its review of 90% of resubmissions within two or six months after receipt, depending on the type of information included. 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 may issue an approval letter. An approval



letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

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, including a black boxed warning, 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 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, certain circumstances may require FDA notification, review, or approval, as well as further testing. These may include some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, or new safety information

#### *Special FDA Expedited Review and Approval Programs*

The FDA has various programs, including fast track designation, accelerated approval, priority review and breakthrough designation, 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 or present a significant improvement over existing therapy. 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. The FDA will determine that a product will fill an unmet medical need if the product will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy, safety, or public health factors. If fast track designation is obtained, drug sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. In some cases, a fast track product may be eligible for accelerated approval or priority review.

The FDA may give a priority review designation to drugs that are intended to treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. A priority review means that the goal for the FDA is to review an application in six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs, which typically adds approximately two months to the timeline for review and decision from the date of submission. Products that are eligible for fast track designation may also be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses or conditions and that fill an unmet medical need 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

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describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 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 significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for the fast track designation features as described above, intensive guidance on an efficient drug development program beginning as early as Phase 1 trials, and a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review.

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.

### *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, manufacturing, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product and drug shortages. 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 list drugs manufactured at their facilities with the FDA. These facilities are further subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with GMP and other regulatory requirements. Changes to the manufacturing process are strictly regulated and may require prior approval by the FDA or notification to the FDA before or after being implemented. FDA regulations also require investigation and correction of any deviations from GMP 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 GMP 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 becomes available in 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 Untitled Letters, holds or termination of post-approval clinical trials or FDA debarment;
- delay or refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- regulatory authority, including the FDA, issued safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such products;
- mandated modifications to promotional material or issuance of corrective information;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment, disgorgement and restitution, as well as consent decrees, corporate integrity agreements, deferred prosecution agreements and exclusion from federal healthcare programs.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies are prohibited from marketing or promoting their drug products for uses outside of the approved indications in the approved prescribing information. 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 marketed or promoted off-label uses may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs debarment from government contracts and refusal of future orders under existing contracts, and mandatory compliance programs under corporate integrity agreements or deferred prosecution agreements.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act, or PDMA, which, among other things, 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.

Moreover, the recently enacted Drug Quality and Security Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding drug products to individuals and entities to which product ownership is transferred, label drug products with a product identifier, and keep certain records regarding drug products. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products such that they would result in serious adverse health consequences or death, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

*DEA Regulation*

While we currently do not know whether any of our product candidates will be considered to be controlled substances, we will be required to evaluate the abuse potential of our product candidates. If any of our product candidates are considered controlled substances, we will need to comply with additional regulatory requirements.

Certain drug products may be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or CSA, and the United States Drug Enforcement Administration's, or DEA's, implementing regulations. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. FDA provides a recommendation to DEA as to whether a drug should be classified as a controlled substance and the appropriate level of control. If DEA scheduling is required, a drug product may not be marketed until the scheduling process is completed, which could delay the launch of the product.

Depending on the Schedule, drug products may be subject to registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA, which are directly applicable to product applicants, contract manufacturers and to distributors, prescribers and dispensers of controlled substances. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging in order to prevent loss and diversion into illicit channels of commerce.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Records must be maintained for the handling of all controlled substances, and periodic reports may be required to be made to the DEA for the distribution of certain controlled substances. Reports must also be made for thefts or significant losses of any controlled substance. To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings or consent decrees. Individual states also independently regulate controlled substances.

*Federal and State Healthcare related, 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, and other laws regulations, and requirements restrict business practices in the biopharmaceutical industry. These laws include anti-kickback and false claims laws and regulations, state and federal transparency laws regarding payments or other items of value provided to health care professionals, as well as data privacy and security laws and regulations and other requirements

applicable to the healthcare industry, including pharmaceutical manufacturers. There are also laws, regulations, and requirements applicable to the award and performance of federal contracts and grants.

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, in whole or in part, 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, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are narrowly drawn. 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.

The reach of the Anti Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively Affordable Care Act, which, among other things, amended the intent requirement of the federal Anti Kickback Statute and certain provisions of the criminal health care fraud statute (discussed below) 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, the Affordable Care Act provides that the government may assert that a claim for payment for 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. Penalties for violation of the Anti Kickback Statute include criminal fines, imprisonment, civil penalties and damages, exclusion from participation in federal healthcare programs and corporate integrity agreements or deferred prosecution agreements. Conviction or civil judgments are also grounds for debarment from government contracts.

The federal civil 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, including payments under a federal grant. A claim includes "any request or demand" for money or property presented to the United States government. The False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil False Claims Act. Several pharmaceutical and other healthcare companies have been sued under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Companies have also been sued for causing false claims to be submitted because of the companies' marketing of products for unapproved, or off-label, uses. In addition, federal health care programs require drug manufacturers to report drug pricing information, which is used to quantify discounts and establish reimbursement rates. Several pharmaceutical and other healthcare companies have been sued for reporting allegedly false pricing information, which caused the manufacturer to understate rebates owed or, when used to determine reimbursement rates, caused overpayment to providers. Violations of the civil False Claims Act may result in civil penalties and damages as well as exclusion from federal healthcare programs and corporate integrity agreements or deferred prosecution agreements. The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim. Violations of the

criminal False Claims Act can result in criminal fines and/or imprisonment, as well as exclusion from participation in federal healthcare programs. Conviction or civil judgments and other conduct are also grounds for debarment from government contracts and grants.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, 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. As discussed above, the Affordable Care Act amended the intent standard for certain of HIPAA's healthcare fraud provisions 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. Violations of HIPAA's fraud and abuse provisions may result in fines or imprisonment, as well as exclusion from participation in federal healthcare programs, depending on the conduct in question. Also, 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 civil monetary penalties statute imposes penalties against any person or entity who, among other things, 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.

The Veterans Health Care Act requires manufacturers of covered drugs to offer them for sale on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects us to contractual remedies as well as administrative, civil and criminal sanctions.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. The Affordable Care Act created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; and/or require drug manufacturers to track and report information related to payments, gifts and other items of value to physicians and other healthcare providers.

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 for Economic 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. Penalties for violating HIPAA include civil penalties, criminal penalties and imprisonment. Among other things, HITECH, through its implementing regulations, makes HIPAA's privacy and security standards directly applicable to "business associates," defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. 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

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new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws govern the privacy and security of health and other 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 products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

### *Coverage and Reimbursement*

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for our therapeutic product candidates. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payers are increasingly imposing additional requirements and restrictions on coverage, attempting to limit reimbursement levels or regulate the price of drugs and other medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. For example, in the United States, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. Moreover, the Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies.

In addition, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, availability of generic equivalents, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. The cost containment measures that healthcare payers and providers are instituting and any healthcare reform implemented in the future could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

### *Impact of Healthcare Reform on Coverage, Reimbursement, and Pricing*

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription, pharmacy drugs pursuant to federal regulations. Part D plans include both standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. In general, Part D prescription drug plan sponsors have flexibility

regarding coverage of Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class, with certain exceptions. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, any negotiated prices for our future products covered by a Part D prescription drug plan will likely be discounted, thereby lowering the net price realized on our sales to pharmacies. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payers.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payers do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the Affordable Care Act, which became law in March 2010 and substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the Affordable Care Act establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; expansion of Medicaid benefits and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program; and expansion of the 340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers. In the future, there may continue to be additional proposals relating to the reform of the United States healthcare system, some of which could further limit the prices we are able to charge or the amounts of reimbursement available for our product candidates once they are approved.

#### *The Foreign Corrupt Practices Act*

The Foreign Corrupt Practices Act or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting



provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

### ***Exclusivity and Approval of Competing Products***

#### *Hatch-Waxman Patent Exclusivity*

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA, or 505(b)(2) NDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the reference listed drug. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage form or indication.

The ANDA or 505(b)(2) NDA applicant is required to provide a certification to the FDA in the product application concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable, or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed patent or if the listed patent is a patented method of use for which approval is not being sought. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the

earlier of 30 months, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the ANDA applicant or other period determined by a court.

*Hatch-Waxman Non-Patent Exclusivity*

Market and data exclusivity provisions under the FDCA also 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 therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. 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.

*Pediatric Exclusivity.* Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity period described above. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents.

*Orphan Drug Designation and Exclusivity.* The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals annually in the United States, or affecting more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making the drug available in the United States will be recovered from United States sales. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a drug already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same drug as the already approved drug. This hypothesis must be demonstrated to obtain orphan drug exclusivity. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. In addition, if a product receives FDA approval for the indication for which it has orphan designation, the product is generally entitled to orphan drug exclusivity, which

means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. While we have not sought to obtain orphan drug designation for any of our products, we may in the future seek such designation if we determine that the relevant criteria are met.

### ***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.

#### *European Union Drug Approval Process*

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 European Medicines Agency or 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.

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 data 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.

**Legal Proceedings**

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

**Facilities**

Our headquarters are located in Baltimore, Maryland, where we occupy approximately 6,000 square feet of administrative office space. The term of the lease expires January 31, 2019. We have the ability and may expand this office space based on company's growth and employee head-count.

**Employees**

As of August 31, 2015, we had 11 full-time employees, six of whom were primarily engaged in research and development activities and three of whom had an M.D. and/or Ph.D. degree. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

## MANAGEMENT

The following table sets forth the name, age and position of each of our officers and directors.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Blake M. Paterson, M.D.	58	Chief Executive Officer, President and Director
Bernadine Heather Fraser, Ph.D.	47	Vice President, Clinical Operations and Project Management
John J. Kaiser	59	Chief Business Officer
Ronald Marcus, M.D.	57	Chief Medical Officer and Head, Regulatory Affairs
Mariam E. Morris	47	Chief Financial Officer
Eugene A. Bauer, M.D.(3)	73	Director
Isaac Blech(1)	65	Vice Chairman of the Board of Directors
Phil Gutry(1)	42	Director, Audit Committee Chair
Uli Hacksell, Ph.D.(3)	64	Chairman of the Board of Directors, Nominating and Corporate Governance Committee Chair
Magnus Persson, M.D., Ph.D.(1)(2)	54	Director
Behshad Sheldon(2)(3)	52	Director, Compensation Committee Chair

- (1) Appointed as a member of the Audit Committee.
- (2) Appointed as a member of the Compensation Committee.
- (3) Appointed as a member of the Nominating and Corporate Governance Committee effective on the date this registration statement of which this prospectus forms a part is declared effective.

**Blake M. Paterson, M.D.** Dr. Paterson is one of our founders and has served as our Chief Executive Officer, President and a member of our board of directors since May 2011. Prior to joining our company, Dr. Paterson founded Fells Laboratories LLC, a biotechnology company, where he served as Managing Director from January 2011 through May 2011. Since March 2011, Dr. Paterson has served as a part-time faculty member at the Johns Hopkins School of Medicine in the Division of Neuroanesthesia and Neurological Critical Care in the Department of Anesthesia and Critical Care Medicine. From April 2008 through April 2011, Dr. Paterson owned and operated NRZ Consulting LLC, a translational medicine consulting firm. From February 2004 until March 2008, Dr. Paterson served as the Chief Executive Officer and President for Alba Therapeutics Corporation, or Alba Therapeutics, a clinical-stage biopharmaceutical company. He also served on Alba Therapeutics' board of directors during that time. Prior to founding Alba, Dr. Paterson served in various executive positions at Eli Lilly & Company, or Eli Lilly. Prior to joining Eli Lilly, Dr. Paterson was employed by Parke-Davis Pharmaceutical Research. Dr. Paterson received his B.S. in Engineering from Tufts University and his M.D. from the University of Vermont. Our board of directors believes that Dr. Paterson's intimate knowledge of our company, by virtue of his service as our founder and Chief Executive Officer, and his extensive biopharmaceutical industry experience, provides him with the operational expertise, breadth of knowledge and valuable understanding of our industry qualifies him to serve on our board of directors.

**Bernadine Heather Fraser, Ph.D.** Dr. Fraser has served as our Vice President, Clinical Operations and Project Management since October 2012 and Senior Director of Project Management from March 2012 through October 2012. Prior to joining our company, Dr. Fraser served as the Senior Director of Preclinical and Clinical Sciences at Anthera Pharmaceuticals Inc., a biopharmaceutical company, from October 2006 through March 2012. She served in a variety of roles at CV Therapeutics, Inc., a biopharmaceutical company, which was acquired by Gilead Sciences, Inc. in 2009, from June 2000 through October 2006. Dr. Fraser received her B.S. in Zoology from the University of British Columbia, her M.S. in Pharmaceutical Sciences from the University of Montana and her Ph.D. in Pharmacology from the University of Alberta. She has also completed a post-doctoral fellowship at the Johns Hopkins University School of Medicine.

**John J. Kaiser.** Mr. Kaiser has served as our Chief Business Officer since September 2015, as our Chief Commercial Officer from February 2014 to September 2015, and as our Vice President, Commercialization and Business Development from October 2012 to February 2014. Prior to joining our company, Mr. Kaiser served as Senior Director of Business Development & New Ventures of MedAvante, Inc., a global provider of centralized expert psychiatric and neurocognition rating and monitoring services to the pharmaceutical, biotechnology and medical device industries, from July 2011 to September 2012. Mr. Kaiser also founded Denysias Bioscience, LLC, a biopharmaceutical company focused on developing new therapies for neuropsychiatric disorders, where he served as Chief Executive Officer from February 2010 through June 2012. Mr. Kaiser has served as President of Kaiser & Associates Consulting, a boutique consulting firm providing expertise to the biopharmaceutical industry, since November 2009. From February 2008 through November 2009, Mr. Kaiser served as Vice President of Commercial and Business Development at ACADIA Pharmaceuticals Inc., or ACADIA, a specialty pharmaceutical company. Prior to ACADIA, from February 1980 to January 2008, Mr. Kaiser held positions of increasing responsibility at Eli Lilly. Mr. Kaiser received his B.S. in Pharmaceutical Sciences from the James L. Winkle College of Pharmacy at the University of Cincinnati.

**Ronald Marcus, M.D.** Dr. Marcus has served as our Chief Medical Officer and Head, Regulatory Affairs since May 2015. Prior to joining our company, Dr. Marcus served as the Chief Medical Officer of Spinifex Pharmaceuticals, or Spinifex, a clinical-stage biotechnology company, from May 2014 until March 2015. Before joining Spinifex, Dr. Marcus was employed by Bristol-Meyers Squibb for 23 years, where he held a variety of positions including Executive Director of Neuroscience Global Clinical Research and Group Director of Neuroscience Strategic Unit. Dr. Marcus received his B.A. in Psychology from the University of Virginia and his M.D. from SUNY at Buffalo School of Medicine. Dr. Marcus completed a psychiatry residency at Cornell University Medical Center.

**Mariam E. Morris.** Ms. Morris has served as our Chief Financial Officer since August 2015 and prior thereto served as our interim Chief Financial Officer since May 2015. Ms. Morris was the sole proprietor of Mariam Morris CPA, a full service tax, accounting and business consulting firm, which she founded in January 2009 and operated until August 2015. Prior to that, Ms. Morris was the Chief Financial Officer of Sucampo Pharmaceuticals, Inc., from February 2004 to July 2009. From 1991 until 2001, Ms. Morris was an auditor for PricewaterhouseCoopers. Ms. Morris received her B.B.A. in Accounting from Texas Tech University and her M.S. in Taxation from Old Dominion University. Ms. Morris is a Certified Public Accountant in the state of Texas.

**Eugene A. Bauer, M.D.** Dr. Bauer has served on our board of directors since May 2011. Dr. Bauer also co-founded and has served as the Chief Medical Officer and a member of the board of directors of Skintelligence, Inc, now called Dermira, Inc., a dermatology company in the San Francisco Bay Area, since June 2010. Dr. Bauer has also served on the board of directors of Medgenics since March 2001. Dr. Bauer served as the President and Chief Medical Officer of Peplin, Inc., or Peplin, a development-stage dermatology company, from June 2008 through June 2010. Peplin, was acquired by LEO-Pharma in November 2009. Dr. Bauer continued as a consultant with Peplin through June 2010. Dr. Bauer served as the Chief Executive Officer of Neosil, Inc., a development-stage dermatology pharmaceutical company, from 2004 through 2008. Since 2002, Dr. Bauer has served as a Professor (Emeritus) in the School of Medicine at Stanford University. He received his B.S. in Medicine and his M.D. from Northwestern University. Our board of directors believes that Dr. Bauer's strong background of service on the boards of directors of numerous public pharmaceutical companies and his vast industry experience make him a valuable member of our board of directors.

**Isaac Blech.** Mr. Blech has served on our board of directors since March 2011 and as Vice Chairman of our board of directors since March 2012. Until March 2011, Mr. Blech was retired. Mr. Blech currently serves on a variety of boards of directors. Mr. Blech has served on the board of ContraFect Corporation, a biotechnology company, since August 2011 and Medgenics since May 2011.

Mr. Blech has served as Vice Chairman of Edge Therapeutics, Inc. since January 2013, Centrexion Corp, a biotechnology company, since February 2013 and RestorGenex since November 2013. He has also served on the board of The SpendSmart Payments Company, or SpendSmart, an online and retail payment company, since March 2011 and as Vice Chairman since November 2011. Mr. Blech has served on the board of Premier Alliance Group, Inc., or Premier Alliance, an advisory, consulting and resource service company, since June 2011 and as Vice Chairman since May 2012. Prior to joining our board of directors, Mr. Blech played a role in establishing some of the leading biotechnology companies including Celgene, ICOS Corporation, Pathogenesis Corporation, Nova Pharmaceutical Corporation and Genetic Systems Corporation. Mr. Blech received his B.A. in Medicine from Baruch College. Our board of directors believes that Mr. Blech's experience as a director of several biotechnology and pharmaceutical companies and his experience as a director of a public biopharmaceutical company gives him the qualifications, skills and financial expertise to serve on our board of directors.

**Phil Gutry.** Mr. Gutry has served on our board of directors since April 2015. Since July 2015, Mr. Gutry has served as Senior Director of business development at Regeneron Pharmaceuticals, Inc., an integrated biopharmaceutical company. From May 2011 to June 2015, Mr. Gutry served as a Principal of MPM Capital, Inc., or MPM, a venture capital firm with a focus on the life sciences industry. Prior to joining MPM, Mr. Gutry worked in the Corporate Development Group at Gilead Sciences, Inc., a research-based biopharmaceutical company, for approximately five years. Mr. Gutry previously worked at Riverside Partners, LLC, a healthcare focused private equity investment firm, and at The Wilkerson Group. Mr. Gutry received his A.B. in Earth Sciences from Dartmouth College and an M.B.A. in Healthcare Management from The Wharton School. Our board of directors believes that Mr. Gutry's experience in the biopharmaceutical industry and in venture capital makes him a valuable member of our board of directors.

**Uli Hacksell, Ph.D.** Dr. Hacksell has served as the Chairman of our board of directors since May 2015. From September 2000 to March 2015, Dr. Hacksell served as the Chief Executive Officer and as a director of ACADIA Pharmaceuticals Inc., or ACADIA. From February 1999 to September 2000, he served as our Executive Vice President of Drug Discovery of ACADIA. Dr. Hacksell held various senior executive positions at Astra AB, or Astra, a pharmaceutical company, including Vice President of Drug Discovery and Technology as well as President of Astra Draco AB, one of Astra's largest research and development subsidiaries, where he directed an organization of more than 1,100 employees. He also served as Vice President of CNS Preclinical R&D at Astra Arcus, another Astra subsidiary. Earlier in his career, Dr. Hacksell held the positions of Professor of Organic Chemistry and Department Chairman at Uppsala University in Sweden and also served as Chairman and Vice Chairman of the European Federation of Medicinal Chemistry. Dr. Hacksell received his Master of Pharmacy and a Ph.D. in Medicinal Chemistry from Uppsala University. Our board of directors believes that Dr. Hacksell brings to the board substantial leadership skills and scientific background that are helpful in its discussions for determining the company's growth strategy and business plans. Furthermore, Dr. Hacksell's leadership abilities and experience make him particularly well qualified to be our Chairman.

**Magnus Persson, M.D., Ph.D.** Dr. Persson has served on our board of directors since August 2012. Since September 2013, Dr. Persson has served as a Director at Scandinavian Node InnoLIFE at the Karolinska Institutet in Stockholm, Sweden, where he has also served as an Associate Professor in Physiology since September 1994. Dr. Persson has served as a practicing pediatrician at CityAkuten in Stockholm, Sweden since December 2012. He is also currently the Chief Executive Officer of C10Pharma AS in Oslo, Norway, a preclinical-stage pharmaceutical company, a position he has held since December 2012. Prior to joining our board of directors, Dr. Persson served as a Partner at HealthCap, a Swedish-based venture capital firm, from January 2008 through December 2009, and as a Managing Partner at The Column Group, a San Francisco-based venture capital firm, from January

2010 through November 2011. From November 2011 until September 2013, Dr. Persson was a Physician at Stockholms Läns Landsting in Stockholm, Sweden. Dr. Persson founded Aerocrine AB, a medical technology company in 1994. Dr. Persson has also served on the boards of Contera AS, a biotechnology company, since December 2011, Karolinska Institutet Innovations AB, a technology transfer company, since December 2011, Galecto AB, a biotechnology company, since January 2013, AscendxSpine Inc., a medical device company, since December 2012, BioWorks AB, a laboratory equipment company, since July 2013 and SLS Ventures AB, a life science venture capital firm since March 2012. Dr. Persson received his M.D. and Ph.D. in physiology from Karolinska Institutet. Our board of directors believes that Dr. Persson's extensive experience in medicine, life sciences and biotechnology financing and his experience founding and leading private as well as public biotechnology and medical technology companies make him a valuable member of our board of directors who will assist in the development of our growth strategy and business plans.

**Behshad Sheldon.** Ms. Sheldon has served on our board of directors since July 2014. Ms. Sheldon currently serves as a partner of Apple Tree Partners IV, L.P. and the President and Chief Executive Officer of Braeburn Pharmaceuticals, Inc., or Braeburn, a biopharmaceutical company focusing on developing and commercializing products for neurological and psychiatric disorders. Prior to joining Braeburn in September of 2012, Ms. Sheldon served in a variety of roles over a 10 year period at Otsuka Pharmaceutical Co., Ltd., or Otsuka, with her most recent position being Senior Vice President, Patient & Branding Strategy and a member of the board of directors of Otsuka's research and development organization. Prior to Otsuka, Ms. Sheldon held positions with increasing responsibility at SmithKline Beecham Corporation and Bristol-Myers for over 16 years. Ms. Sheldon received her B.S. degree in Neuroscience from the University of Rochester. With more than 27 years of pharmaceutical industry experience, our board of directors believes Ms. Sheldon's extensive expertise in pharmaceutical product development, commercialization and marketing and track record of producing products such as Abilify, Plavix and Glucophage, gives her the qualifications and skills to serve on our board of directors.

## **Board Composition and Election of Directors**

### ***Board Composition***

Our board of directors currently consists of seven members, each of whom are elected pursuant to the board composition provisions of our current certificate of incorporation and our stockholders agreement, which agreement is described under "Certain Relationships and Related Party Transactions" in this prospectus. These board composition provisions will terminate upon the closing of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity. We have no formal policy regarding board diversity. Our nominating and corporate governance committee's and board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, and professional and personal experiences and expertise relevant to our growth strategy.

Immediately following the closing of this offering, our board of directors will be divided into three staggered classes of directors of the same or nearly the same number and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2016 for Class I directors, 2017 for Class II directors and 2018 for Class III directors.



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- Our Class I directors will be Eugene Bauer and Magnus Persson;
- Our Class II directors will be Isaac Blech and Phil Gutry; and
- Our Class III directors will be Blake Paterson, Uli Hacksell and Behshad Sheldon.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our 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 shall consist of one third of the board of directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

### ***Director Independence***

Rule 5605 of the NASDAQ Marketplace Rules, or the NASDAQ Listing Rules, requires that a company listing in connection with its initial public offering must meet the following requirements (1) for its audit, compensation and nominating committees, (a) one member satisfying the independence requirements applicable to such committees described below at the time of listing, (b) a majority of members satisfying such requirements within 90 days of listing, and (c) all members satisfying such requirements within one year of listing; and (2) independent directors compose a majority of the listed company's board of directors within one year of listing. In addition, the NASDAQ Listing Rules require that, subject to specified exceptions, each member of a listed company's audit committee, compensation committee, and nominating committee (to the extent that the listed company select or recommend director nominees through a nominating committee instead of independent directors constituting a majority of the board of directors' independent directors), be independent and that audit committee members and compensation committee members also satisfy additional independence criteria. Under NASDAQ Listing Rule 5605(a)(2), a director will only qualify as an "independent director" if the person meets the independence criteria listed therein and, in the opinion of our 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. Under NASDAQ Listing Rule 5605(c)(2), audit committee members must also meet the independence criteria set forth in Rule 10A 3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, under which 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. Under NASDAQ Listing Rule 5605(d)(2), members of the compensation committee must also satisfy additional independence requirements: under which the board of directors of the listed company must consider, in affirmatively determining the independence of a director who will serve on the compensation committee, all factors specifically relevant to determining whether a director has a relationship to the listed company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to, the source of compensation of such director, including any consulting, advisory or other compensatory fee from the listed company, and whether the compensation committee member is affiliated with the listed company, any of its subsidiaries or an affiliate of a subsidiary of the listed company.

In June 2015, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family and other relationships, including those relationships described under "Transactions

with Related Persons," our board of directors determined that each of our directors, with the exception of Dr. Paterson, is an "independent director" as that term is defined under Rule 5605(a)(2) of the NASDAQ Listing Rules. Dr. Paterson is not considered independent because he currently serves as our President and Chief Executive Officer. Our board of directors also determined that each member of the audit, compensation and nominating and corporate governance committees satisfies the independence standards for such committees established by the SEC and the NASDAQ Listing Rules. In making these determinations regarding the independence of our directors, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

## **Board Leadership Structure and the Role of the Board in Risk Oversight**

### ***Board Leadership Structure***

The positions of our chairman of the board of directors and chief executive officer are separated. Separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairman of the board of directors to lead our board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer must devote to his position in the current business environment, as well as the commitment required to serve as our chairman of the board of directors, particularly as our board of directors' oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the independent directors in the oversight of the company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors.

Although our amended and restated bylaws that will be in effect immediately prior to the closing of this offering will not require that we separate the chairman of the board of directors and chief executive officer positions, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time. Our board recognizes that depending on the circumstances, other leadership models, such as combining the role of chairman of the board of directors with the role of chief executive officer, might be appropriate. Accordingly, our board may periodically review its leadership structure. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure.

Our independent directors will meet alone in an executive session at no less than four regular meetings of our board of directors each year. The chairman of our board may call additional executive sessions of the independent directors at any time, and the chairman of our board shall call an executive session at the request of a majority of the independent directors. The purpose of these executive sessions is to promote open and candid discussion among non-employee directors.

### ***Role of the Board in Risk Oversight***

We face a number of risks, including those described under the caption "Risk Factors" contained elsewhere in this prospectus. Our board of directors believes that risk management is an important part of establishing, updating and executing the company's business strategy. Our board of directors, as a whole and at the committee level, has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations, and the financial condition and performance of the company. Our board of directors focuses its oversight on the most significant risks facing the company and on its processes to identify, prioritize, assess, manage and mitigate those risks. Our board of directors and its committees receive regular reports from members of the company's senior management on areas of material risk to the company, including strategic, operational, financial, legal and regulatory risks. While our board of directors has an oversight role, management is principally

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tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on the company.

The audit committee, as part of its responsibilities, oversees the management of financial risks, including accounting matters, liquidity and credit risks, corporate tax positions, insurance coverage, and cash investment strategy and results. The audit committee is also responsible for overseeing the management of risks relating to the performance of the company's internal audit function, if required, and its independent registered public accounting firm, as well as our systems of internal controls and disclosure controls and procedures. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation and overall compensation and benefit strategies, plans, arrangements, practices and policies. The nominating and corporate governance committee oversees the management of risks associated with our overall compliance and corporate governance practices, and the independence and composition of our board of directors. These committees provide regular reports, on at least a quarterly basis, to the full board of directors.

### **Committees of the Board**

Our board of directors has established a standing audit committee and compensation committee, and effective on the date this registration statement of which this prospectus forms a part is declared effective, we will establish a nominating and corporate governance committee. The composition and responsibilities of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board.

#### ***Audit Committee***

The audit committee is responsible for assisting our board of directors in its oversight of the integrity of our financial statements, the qualifications and independence of our independent auditors, and our internal financial and accounting controls. The audit committee has direct responsibility for the appointment, compensation, retention (including termination) and oversight of our independent auditors, and our independent auditors report directly to the audit committee. The audit committee also prepares the audit committee report that the SEC requires to be included in our annual proxy statement.

The members of the audit committee are Mr. Gutry, Mr. Blech and Dr. Persson. Mr. Gutry serves as chair of the audit committee. Each member of the audit committee qualifies as an independent director under the corporate governance standards of the NASDAQ Listing Rules and the independence requirements of Rule 10A-3 of the Exchange Act. Our board of directors has determined that Mr. Gutry qualifies as an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulation S-K and meets the financial sophistication requirements of the NASDAQ Listing Rules. The audit committee has adopted a written charter that satisfies the applicable standards of the SEC and the NASDAQ Listing Rules, which we will post on our website upon the closing of this offering.

#### ***Compensation Committee***

The compensation committee approves the compensation objectives for the company, approves the compensation of the chief executive officer and approves or recommends to our board of directors for approval the compensation of other executives. The compensation committee reviews all compensation components, including base salary, bonus, benefits and other perquisites.

The members of the compensation committee are Ms. Sheldon and Dr. Persson. Ms. Sheldon serves as chair of the compensation committee. Each member of the compensation committee is a non-employee director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act, each is an outside director as defined by Section 162(m) of the United States Internal Revenue

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Code of 1986, as amended, or the Code, and each is an independent director as defined by the NASDAQ Listing Rules, including NASDAQ Listing Rule 5605(d)(2). The compensation committee has adopted a written charter that satisfies the applicable standards of the SEC and the NASDAQ Listing Rules, which we will post on our website upon the closing of this offering.

***Nominating and Corporate Governance Committee***

Effective on the date this registration statement of which this prospectus forms a part is declared effective, the nominating and corporate governance committee will be responsible for making recommendations to our board of directors regarding candidates for directorships and the structure and composition of our board and the board committees. In addition, the nominating and corporate governance committee will be responsible for developing and recommending to our board corporate governance guidelines applicable to the company and advising our board on corporate governance matters.

Effective on the date this registration statement of which this prospectus forms a part is declared effective, the members of the nominating and corporate governance committee will be Dr. Hacksell, Dr. Bauer and Ms. Sheldon. Dr. Hacksell will serve as chair of the nominating and corporate governance committee. Each member of the nominating and corporate governance committee will be an independent director as defined by the NASDAQ Listing Rules. The nominating and corporate governance committee has adopted a written charter that satisfies the applicable standards of the NASDAQ Listing Rules, effective on the date this registration statement of which this prospectus forms a part is declared effective and which we will post on our website upon the closing of this offering.

**Code of Business Conduct and Ethics**

We will adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon the closing of this offering, we will post the code of business conduct and ethics on our website. We intend to disclose future amendments to the code or any waivers of its requirements on our website to the extent permitted by the applicable rules and Exchange Act requirements.

**Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee has ever been an officer or employee of the company. None of our executive officers serves, or has served since inception, as a member of the board of directors, compensation committee or other board committee performing equivalent functions of any entity that has one or more executive officers serving as one of our directors or on our compensation committee.

## EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table" below. In 2014, our chief executive officer and our two other highest-paid executive officers, or our named executive officers, were as follows:

- Blake M. Paterson, M.D., President and Chief Executive Officer
- James Vornov, M.D., Ph.D., Chief Medical Officer (Dr. Vornov's employment with the company ended on January 9, 2015)
- John Kaiser, Chief Business Officer

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

### Summary Compensation Table

The following table sets forth information for the years ended December 31, 2013 and 2014, regarding compensation awarded to or earned by our named executive officers.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)(1)</u>	<u>Option Awards (\$)(2)</u>	<u>All Other Compensation (\$)(3)</u>	<u>Total (\$)</u>
Blake M. Paterson, M.D. President and Chief Executive Officer	2014	390,000	199,063	96,793	218	686,074
	2013	325,000	—	—	218	325,218
James Vornov, M.D., Ph.D. Chief Medical Officer(4)	2014	315,000	131,250	38,115	218	484,583
	2013	300,000	—	—	218	300,218
John Kaiser Chief Business Officer	2014	290,700	116,494	45,738	218	453,150
	2013	285,000	—	40,360	129,381	454,741

- (1) Each of our named executive officers received a one-time bonus in connection with the issuance of the Series B convertible preferred stock pursuant to the terms of a letter agreement entered between the company and each named executive officer.
- (2) The amounts reflect the grant date fair value for option awards granted during 2013 and 2014 in accordance with FASB Topic ASC 718. Compensation will only be realized to the extent the market price of our common stock is greater than the exercise price of such option award. For a detailed description of the assumptions used for purposes of determining the grant date fair value, see Note 11 to the financial statements included elsewhere in this prospectus.
- (3) Amount represents the premium amount paid by us for life insurance for each of our named executive officers. For Mr. Kaiser, for the 2013 fiscal year, the amount also consists of a reimbursement of Mr. Kaiser's temporary living expenses for up to six months totaling an aggregate amount of \$29,163 and a one time relocation bonus of \$100,000.
- (4) Dr. Vornov's employment with the company ended on January 9, 2015.

### Narrative to Summary Compensation Table

We review compensation annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, individual performance as compared to our expectations and

objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company.

Our board of directors has historically determined our executives' compensation. Our compensation committee typically reviews and discusses management's proposed compensation with the chief executive officer for all executives other than the chief executive officer. Based on those discussions and its discretion, the compensation committee then recommends the compensation for each executive officer. Our board of directors, without members of management present, discusses the compensation committee's recommendations and ultimately approves the compensation of our executive officers. To date, our compensation committee has used Radford data, with or without a compensation consultant from Radford, for privately held, similarly sized, biotech companies for purposes of determining executive compensation. The compensation committee has used the 50th percentile for bonus and the 75th percentile for equity for the 2013 fiscal year and there were no changes made for the 2014 fiscal year. We engaged Radford as our compensation consultant. Based on Radford's recommendations, our compensation committee and board of directors approved base salaries and target discretionary bonuses described below.

### Annual Base Salary

The following table presents the base salaries for each of our named executive officers for the 2014 and 2015 fiscal years.

Name	2014	Pre-IPO	Post-IPO
	Base Salary	2015	Base Salary
	(\$)	Base Salary	Base Salary
		(\$)(1)	(\$)
Blake M. Paterson, M.D.	390,000	390,000	415,000
James Vornov, M.D., Ph.D.(1)	315,000	315,000	—
John Kaiser	290,700	290,700	297,000

(1) Dr. Vornov's employment with the company ended on January 9, 2015.

### Annual Bonus

Our discretionary bonus plan motivates and rewards our executives for achievements relative to our goals and expectations for each fiscal year. None of our named executive officers received a bonus relative to achievement of goals for the 2014 fiscal year, although our executives did receive a bonus during the 2014 fiscal year following the issuance of our Series B convertible preferred stock for foregoing salary prior to the consummation of the issuance. Following the effective date of the registration statement for this offering, Dr. Paterson's target bonus will be 50% of his base salary and Mr. Kaiser's target bonus will be 30% of his base salary.

### Long-Term Incentives

Our 2011 Stock Incentive Plan authorizes us to make grants to eligible recipients of non-qualified stock options, incentive stock options, restricted stock awards, restricted stock units and other forms of awards, such as stock appreciation rights. While we have made restricted stock awards to our executive officers in the past, our equity grants during 2014 to our executive officers were only in the form of stock options.

Our board of directors adopted a new 2015 Omnibus Incentive Compensation Plan, or 2015 Omnibus Plan, which was approved by our stockholders on August 31, 2015, and is described in more detail under "—2011 Stock Incentive Plan and 2015 Omnibus Incentive Compensation Plan." The 2015 Omnibus Plan will become effective upon the business day immediately preceding the date on which

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the registration statement is declared effective by the SEC and will replace our 2011 Stock Incentive Plan.

### Other Compensation

All amounts shown in the "All Other Compensation" column in the Summary Compensation Table relate to premiums paid by us for life insurance policies for Mr. Paterson, Mr. Vornov and Mr. Kaiser.

### Employment Arrangements

Please see "—Offer Letters" for information regarding the employment and severance agreements for each of our named executive officers.

### Outstanding Equity Awards at 2014 Fiscal Year End Table

The following table presents information regarding all outstanding stock options held by each of our named executive officers on December 31, 2014.

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date
Blake Paterson	5/8/2012	71,428	35,714(1)	\$ 8.68	2/28/2022
	7/10/2014	54,353	—(2)	\$ 16.80	2/28/2024
James Vornov	11/9/2012	9,523	4,761(3)	\$ 8.68	10/31/2022
	7/10/2014	16,071	—(2)	\$ 10.08	2/28/2024
John J. Kaiser	11/9/2012	9,523	4,761(3)	\$ 8.68	10/31/2022
	8/29/2013	2,380	4,761(4)	\$ 8.96	5/31/2023
	7/10/2014	19,285	—(2)	\$ 10.08	2/28/2024

- (1) Such stock option vests in four equal annual installments on each February 24 occurring in 2012, 2013, 2014 and 2015.
- (2) Such stock options were fully vested on the date of grant.
- (3) Such stock option vests in four equal annual installments on each October 15 occurring in 2012, 2013, 2014 and 2015. The shares of our common stock underlying such stock option were forfeited in connection with Dr. Vornov's resignation.
- (4) Such stock option vests in four equal annual installments on each May 6 occurring in 2013, 2014, 2015 and 2016.

### Offer Letters

#### **Blake M. Paterson, M.D.**

Dr. Paterson entered into an offer letter with the company effective May 1, 2011. The offer letter provides for an annual base salary of \$250,000, with an automatic increase to \$275,000, effective May 1, 2012, and another automatic increase to \$300,000, effective May 1, 2013. Dr. Paterson's annual base salary may be further increased from time to time. Dr. Paterson's base salary as of December 31, 2014 was \$ 390,000. Upon execution of the offer letter, Dr. Paterson was entitled to receive a \$100,000 signing bonus. In addition, Dr. Paterson is eligible to receive a discretionary annual bonus as determined by our board of directors or the compensation committee of the board, referred to the compensation committee, in its sole discretion, provided that Dr. Paterson is employed by the company

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on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid to chief executive officers of similarly situated companies in the biotechnology industry, subject to corporate and individual performance. The offer letter provides that Dr. Paterson agreed to purchase 107,142 shares of restricted common stock, which restricted stock was subject to vesting as to one third of the shares on May 1 of each of 2012, 2013 and 2014, subject to Dr. Paterson's continued employment on the applicable vesting dates and the terms of the 2011 Stock Incentive Plan. However, in September 2011, the restrictions were modified so that all of the shares vested at that time.

Pursuant to the terms of Dr. Paterson's offer letter, if Dr. Paterson's employment is terminated for any reason, then the company will pay Dr. Paterson his base salary, bonus and expenses accrued, but unpaid as of the date of his termination, and any benefits accrued and due under any applicable benefit plans and programs of the company.

If Dr. Paterson's employment is terminated on account of his death or disability, and provided that Dr. Paterson complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company in the case of termination on account of disability, he will be entitled to a pro rata average bonus, which for purposes of the offer letter means the average of the annual full-year cash bonuses he received from the company for the three completed calendar years prior to termination (or fewer full year periods if the employment term is less than three years, with 2011 being deemed a full year of service and any prorated bonus paid for 2011 being adjusted upward for the full year for purposes of such calculation), prorated for the portion of the year in which such termination occurred, paid over 12 equal monthly installments.

If Dr. Paterson's employment is terminated by the company without cause or by Dr. Paterson for good reason, provided he complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company, Dr. Paterson is entitled to an amount equal to the sum of (i) 12 months of his then-current base salary and (ii) a pro rata average bonus, payable in 12 equal monthly installments. In addition, Dr. Paterson is entitled to company-paid COBRA premiums for 12 months or until he is eligible for substantially equal coverage, and full vesting of the restricted stock award purchased in connection with his commencement of employment and any future stock option or stock award.

The offer letter provides that at all times during Dr. Paterson's employment and thereafter, Dr. Paterson will maintain the confidentiality of all confidential information obtained by him as a result of his employment with the company, assign all inventions and not disparage the company or any of its officers, directors, employees, shareholders or products. In addition, during the term of Dr. Paterson's employment with the company, and for the 12 month period after Dr. Paterson's termination of employment, Dr. Paterson cannot (i) compete against the company, (ii) interfere with the relationships between the company and any of its subsidiaries, affiliates or any of their respective vendors or licensors, or (iii) recruit in any way the employees of the company.

***James Vornov, M.D., Ph.D.***

Dr. Vornov entered into an offer letter with the company effective October 15, 2012. The offer letter provides for an annual base salary of \$300,000, which, beginning February 2014, will be reviewed annually and may be increased by our board of directors. Dr. Vornov is eligible to receive a discretionary annual bonus as determined by our board of directors or the compensation committee, in its sole discretion, provided that Dr. Vornov is employed by the company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid the executives of similar grade of similarly situated companies on the biotechnology industry, subject to corporate and individual performance. In addition, the offer letter provides that, subject to approval by our board of directors, Dr. Vornov will receive a stock option to



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purchase 14,285 shares of common stock, which is subject to vesting as to one third of the shares on October 15 of each of 2013, 2014 and 2015, subject to Dr. Vornov's continued employment on the applicable vesting dates and the terms of the 2011 Stock Incentive Plan.

Pursuant to the terms of Dr. Vornov's offer letter, if Dr. Vornov's employment is terminated for any reason, then the company will pay Dr. Vornov his base salary, bonus and expenses accrued, but unpaid as of the date of his termination, and any benefits accrued and due under any applicable benefit plans and programs of the company. Dr. Vornov's resigned from his employment with the company on January 9, 2015 and was paid salary and accrued vacation through such date.

The offer letter provides that at all times during Dr. Vornov's employment and thereafter, Dr. Vornov will maintain the confidentiality of all confidential information obtained by him as a result of his employment with the company, assign all inventions and not disparage the company or any of its officers, directors, employees, shareholders or products. In addition, during the term of Dr. Vornov's employment with the company, and for the 12 month period after Dr. Vornov's termination of employment, Dr. Vornov cannot (i) compete against the company, (ii) interfere with the relationships between the company and any of its subsidiaries, affiliates or any of their respective vendors or licensors, or (iii) recruit in any way the employees of the company.

***John Kaiser***

Mr. Kaiser entered into an offer letter with the company effective October 15, 2012. The offer letter provides for an annual base salary of \$285,000. Mr. Kaiser's annual base salary may be further increased from time to time. In connection with Mr. Kaiser's commencement of employment, he was entitled to reimbursement of temporary living expenses up to six months, and a relocation bonus of \$100,000. A pro-rata portion of the relocation bonus must be repaid to the company if his employment is terminated for cause or he resigns voluntarily within 18 months after commencement of employment. Mr. Kaiser is eligible to receive a discretionary annual bonus as determined by our board of directors or the compensation committee, in its sole discretion, provided that Mr. Kaiser is employed by the company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid the executives of similar grade of similarly situated companies on the biotechnology industry, subject to corporate and individual performance. In addition, the offer letter provides that, subject to approval by our board of directors, Mr. Kaiser will receive a stock option to purchase 14,285 shares of common stock, which is subject to vesting as to one third of the shares on October 15 of each of 2013, 2014 and 2015, subject to Mr. Kaiser's continued employment on the applicable vesting dates and the terms of the 2011 Stock Incentive Plan.

Pursuant to the terms of Mr. Kaiser's offer letter, if Mr. Kaiser's employment is terminated for any reason, then the company will pay Mr. Kaiser his base salary, bonus and expenses accrued, but unpaid as of the date of his termination, and any benefits accrued and due under any applicable benefit plans and programs of the company.

If Mr. Kaiser's employment is terminated by the company without cause or by Mr. Kaiser for good reason, provided he complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company, Mr. Kaiser is entitled to an amount equal to 12 months of his then-current base salary, payable in 12 equal monthly installments. In addition, Mr. Kaiser is entitled to company-paid COBRA premiums for 12 months or until he is eligible for substantially equal coverage, and full vesting of the stock option award.

The offer letter provides that at all times during Mr. Kaiser's employment and thereafter, Mr. Kaiser will maintain the confidentiality of all confidential information obtained by him as a result of his employment with the company, assign all inventions and not disparage the company or any of its officers, directors, employees, shareholders or products. In addition, during the term of Mr. Kaiser's employment with the company, and for the 12 month period after Mr. Kaiser's termination of

employment, Mr. Kaiser cannot (i) compete against the company, (ii) interfere with the relationships between the company and any of its subsidiaries, affiliates or any of their respective vendors or licensors, or (iii) recruit in any way the employees of the company.

For purposes of the offer letters, termination for "good reason" generally means a termination initiated by the employee in response to one or more of the following events: (i) a material diminution in the employee's duties, authorities or responsibilities, (ii) a requirement by the company that the employee's principal place of work be permanently moved to a location more than 50 miles away from Baltimore, Maryland, or (iii) the company material breach of the offer letter, including a diminution of base salary. In order for a termination to be on account of good reason, the employee must notify the company of his intention to terminate for good reason, the company has an opportunity to cure the action or omission that constitutes the ground for good reason and the named executive officer must terminate employment for good reason shortly after the end of the company's cure period. In addition, Mr. Kaiser may invoke good reason in the event that the company fails to nominate him as a member of our board of directors. The employee is required to provide the company with a written notice detailing the specific circumstances alleged to constitute good reason within 30 days after the first occurrence of such circumstances, and the company shall have 30 days following the receipt of such notice to cure the alleged good reason event.

Termination for "cause" generally includes the following: (i) the employee's willful misconduct or gross negligence in the performance of his duties to the company not cured within 30 days after notice, (ii) the employee's failure to perform his duties to the company or to follow the lawful directives of our board of directors that is not cured within 30 days after notice, (iii) the employee's commission of, indictment for, conviction of, or pleading of guilty or nolo contendere to, a felony or any crime involving moral turpitude, or (iv) any act of theft, fraud, malfeasance or dishonesty in connection with the performance of the employee's duties to the company, or (v) a material breach of the offer letter or any other agreement with the company, or a material violation of the company's code of conduct or other written policy that is not cured within 30 days after notice.

## **2011 Stock Incentive Plan and 2015 Omnibus Incentive Compensation Plan**

### ***2011 Stock Incentive Plan***

Our board of directors and stockholders adopted the 2011 Stock Incentive Plan on April 28, 2011. The 2011 Stock Incentive Plan was amended on January 10, 2012 and on May 6, 2013 to increase the number of shares authorized for issuance thereunder. On June 26, 2015, our board of directors adopted the 2015 Omnibus Plan, which was approved by our stockholders on August 31, 2015. Our 2015 Omnibus Plan will become effective upon the business day immediately preceding the date on which the registration statement is declared effective by the SEC.

As of the effective date of our 2015 Omnibus Plan, our 2011 Stock Incentive Plan will be merged with and into our 2015 Omnibus Plan and no additional grants will be made thereafter under our 2011 Stock Incentive Plan. Outstanding grants under our 2011 Stock Incentive Plan will continue in effect according to their terms as in effect before our 2015 Omnibus Plan merger, and the shares with respect to outstanding grants under our 2011 Stock Incentive Plan will be issued or transferred under our 2015 Omnibus Plan.

### ***Types of Stock Awards***

The 2011 Stock Incentive Plan provides for the grant of stock options (incentive stock options and non-qualified stock options), restricted stock awards and other stock-based awards, which are collectively referred to as stock awards. Other stock-based awards are awards of common stock and other awards (including cash) that are valued in whole or in part by reference to, or are payable in or otherwise based on, our common stock and may include, without limitation, restricted stock units,

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performance share awards or an award valued by reference to an affiliate of the company. Stock awards may be granted to employees, including officers, non-employee directors and consultants of the company or our affiliates, except that incentive stock options may be granted only to employees.

### *Share Reserve*

The aggregate number of shares of our common stock that have been reserved for issuance under the 2011 Stock Incentive Plan is 704,428 shares. The number of shares of our common stock available for future issuance under our 2011 Stock Incentive Plan will be available for issuance under our 2015 Omnibus Plan upon the effectiveness of the 2015 Omnibus Plan. If a stock award granted under the 2011 Stock Incentive Plan expires, terminates, is canceled or is forfeited for any reason, the number of shares subject to the stock award will again be available for purposes of stock awards under the 2011 Stock Incentive Plan. In addition, if stock awards are settled in cash, the share reserve will be reduced by the number of shares of common stock with a value equal to the amount of the cash distributions as of the time that such amount was determined and if stock options are exercised using net exercise, the share reserve will be reduced by the gross number of shares of common stock subject to the exercised portion of the option. Since inception 465,939 shares have been granted under the 2011 Stock Incentive Plan and 167,857 shares have been granted outside of the 2011 Stock Incentive Plan.

### *Administration*

Our board of directors or a duly authorized committee thereof, has the authority to administer the 2011 Stock Incentive Plan. Subject to the terms of the 2011 Stock Incentive Plan, our board of directors or the authorized committee, referred to herein as the committee, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the committee will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award. The committee has the authority to modify outstanding awards under the 2011 Stock Incentive Plan. The committee has the authority to adopt, alter and repeal administrative rules, guidelines and practices governing the 2011 Stock Incentive Plan and to perform all other acts, including delegating administrative responsibilities, as it deems advisable to construe and interpret the terms and provisions of the 2011 Stock Incentive Plan and any stock award granted under the 2011 Stock Incentive Plan. Decisions and interpretations or other actions by the committee are in the discretion of the committee and are final binding and conclusive on the company and all participants in the 2011 Stock Incentive Plan.

### *Stock Options*

Incentive stock options and non-qualified stock options are granted pursuant to stock option agreements adopted by the committee. The committee determines the exercise price for a stock option, within the terms and conditions of the 2011 Stock Incentive Plan, provided that the exercise price of a stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2011 Stock Incentive Plan will become exercisable at the rate specified by the committee and may be exercisable for restricted stock, if determined by the committee.

The committee determines the term of stock options granted under the 2011 Stock Incentive Plan, up to a maximum of ten years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, or voluntary resignation, the option holder may generally exercise any vested options for a period of 90 days following the cessation of service. If the options holder's service relationship terminates due to voluntary resignation, the option holder may generally exercise any vested options for a period of 30 days following cessation of service. The option term may

be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an option holder's service relationship with us or any of our affiliates ceases due to disability or death, or an option holder dies within a certain period following cessation of service, the option holder or a beneficiary may generally exercise any vested options for a period of one year following the option holder's disability or death. Unless otherwise provided by the committee at the time a stock option is granted, in the event of a termination for cause, or the participant violates certain restrictive covenants, including but not limited to, nondisclosure of confidential information, non-solicitation, non-competition and non-disparagement provisions set forth in the 2011 Stock Incentive Plan, referred to as detrimental activity, in any case, before the stock option is exercised, then the stock option will terminate. If an option holder engages in detrimental activity within one year following the later of the date the stock option is exercised or becomes vested, then option holder must pay back to the company any gain realized as a result of exercise. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the committee and may include (i) cash, check, bank draft or money order, (ii) if the company's common stock is publicly traded, a broker-assisted cashless exercise, or (iii) such other methods as may be approved by the committee, including without limitation, the tender of shares of our common stock previously owned by the option holder or a net exercise of the option.

Unless the committee provides otherwise, options generally are not transferable except by will, the laws of descent and distribution. The committee may provide that a non-qualified stock option may be transferred to a family member, as such term is defined under the applicable securities laws.

The committee may at any time offer to buy out a stock option previously granted, based on the terms established by the committee and communicated to the option holder at the time the offer is made.

#### *Tax Limitations on Incentive Stock Options*

The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options that are exercisable for the first time by an option holder during any calendar year may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as non-qualified stock options. No incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (ii) the term of the incentive stock option does not exceed five years from the date of grant.

#### *Restricted Stock Awards*

Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the committee. Restricted stock awards may be granted for a purchase price, or no purchase price, and either alone or in addition to other stock awards granted under the 2011 Stock Incentive Plan. The committee determines the purchase price, if any, the vesting schedule, if any, and the rights to acceleration of any vesting schedule, and all other terms and conditions of each restricted stock award. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the committee. Rights to acquire shares under a restricted stock award may not be transferred. Except as otherwise provided in the applicable award agreement, restricted stock unit awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Unless otherwise provided by the committee at the time a restricted stock award is granted, in the event a participant engages in detrimental activity prior to or during the one year period after the

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vesting of restricted stock, the committee may direct that all unvested restricted stock will be immediately forfeited and that the participant must pay to the company an amount equal to the fair market value at the time of vesting of any restricted stock that vested prior to the participant's engagement in the detrimental activity. If an option holder engages in detrimental activity within one year following the later of the date the stock option is exercised or becomes vested, then option holder must pay back to the company any gain realized as a result of exercise. In no event may an option be exercised beyond the expiration of its term.

### *Other Stock Awards*

The committee may grant other awards based in whole or in part by reference to our common stock. The committee will set the number of shares under the stock award and all other terms and conditions of such awards.

### *Changes to Capital Structure*

In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (i) the aggregate number and kind of shares that may be issued under the 2011 Stock Incentive Plan, (ii) the number and/or kind of shares or other property (including cash) that can be issued upon exercise of an outstanding stock award or under other stock awards granted under the plan, and (iii) the purchase price thereof.

### *Acquisition Event*

In the event of an acquisition event, the committee may terminate all outstanding and unexercised stock options or any other stock-based award that provides for a participant to exercise the stock award, effective as of the date of the acquisition event, by delivering notice of termination to each participant at least 20 days prior to the date of consummation of the event. The participant may exercise the stock awards during the notice period, contingent upon the occurrence of the acquisition event, to the extent vested (or without regard to limitation of exercisability, as determined by the committee). All such stock awards not exercised will be forfeited in connection with the acquisition event. The committee retains the right to terminate any such exercisable stock award for which the exercise price is equal to or exceeds the fair market value without payment of consideration therefor.

For purposes of the 2011 Stock Incentive Plan, an acquisition event is a merger or consolidation in which the company is not the surviving entity, any transaction that results in the acquisition of all or substantially all of the company's outstanding common stock by a single person or entity or by a group of persons and/or entities acting in concert, or the sale or transfer of all or substantially all of the company's assets.

### *Change of Control*

In the event of a change of control, the committee has the discretion to take any of the following actions with respect to stock awards:

- arrange for the substitution of a stock award by a surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award; or
- cancel stock awards for fair value, which, in the case of options, may equal the excess, if any, of (a) the value of the property to be received in the change of control to holders of the same number of shares of common stock subject to the stock option, over (b) the exercise price otherwise payable in connection with the stock award.

The committee is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

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Under the 2011 Stock Incentive Plan, a change of control is generally (i) the acquisition by a person or entity, other than a corporation owned directly or indirectly by the stockholders of the company in substantially the same proportions as their ownership of stock of the company, of more than 50% of our combined voting power; (ii) a consummated merger, or consolidation, other than a merger or consolidation which would result in the voting securities of the company outstanding immediately prior thereto continuing to represent the total voting power represented by the voting securities of the company or such surviving entity outstanding immediately after such merger or consolidation; (iii) a consummated sale or other disposition of all or substantially of our assets; or (iv) the dissolution, liquidation or winding up of the company.

### *Company Call Rights; Right of First Refusal; Approved Sale*

Upon termination of employment or service, the company has certain call rights with respect to our common stock obtained through exercise of stock options, through restricted stock or other stock-based awards. The company's purchase price is based on the reason for the participant's termination. In addition, the company has rights of first refusal in the event a participant desires to transfer shares obtained pursuant to an awards under the 2011 Stock Incentive Plan. If the board of directors and stockholders having the requisite voting power at law and under the company's governing documents approve a sale of all or substantially all of the assets of the company or a sale of all or substantially all of the shares of common stock to an independent third party or group of independent third parties, then each holder of shares of common stock issued pursuant to an award under the 2011 Stock Incentive Plan is required to vote for, consent to and raise no objections to such sale, and generally shall be subject to the same terms and restrictions as the other stockholders participating in the sale, referred to as drag-along rights. The company's call rights, right of first refusal and drag-along rights will terminate upon the effectiveness of this offering.

### *Amendment and Termination*

Our board of directors or the committee has the authority to amend, suspend, or terminate the 2011 Stock Incentive Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Unless approved by stockholders, if required, no amendment may increase shares of our common stock available for issuance under the 2011 Stock Incentive Plan, change the classification of individuals eligible to receive stock awards under the 2011 Stock Incentive Plan, decrease the minimum exercise price of stock options, extend the maximum stock option term or require stockholder approval in order to continue to comply with the rules under the Code for incentive stock options.

## **2015 Omnibus Plan**

### *Introduction*

Our 2015 Omnibus Plan was adopted by our board of directors on June 26, 2015 and approved by our stockholders on August 31, 2015. Our 2015 Omnibus Plan will become effective immediately prior to the effective date of the registration statement for this offering.

### *Purpose and Types of Grants*

The purpose of our 2015 Omnibus Plan is to attract and retain employees, non-employee directors and consultants and advisors. Our 2015 Omnibus Plan provides for the issuance of incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights, other stock-based awards and cash bonus awards. Our 2015 Omnibus Plan also provides for the issuance of equity and cash bonus awards that are intended to qualify as "qualified performance-based compensation" for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended, which we refer to as the Internal Revenue Code, to selected executive employees, or qualified performance grants. Our 2015

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Omnibus Plan is intended to provide an incentive to participants to contribute to our economic success by aligning the economic interests of participants with those of our stockholders.

### *Administration*

Our 2015 Omnibus Plan will be administered by our compensation committee, and our compensation committee will determine all of the terms and conditions applicable to grants under our 2015 Omnibus Plan. Our compensation committee will also determine who will receive grants under our 2015 Omnibus Plan and the number of shares of common stock that will be subject to grants, except that grants to members of our compensation committee must be authorized by a disinterested majority of our board of directors.

### *Grants*

Subject to adjustment, our 2015 Omnibus Plan authorizes the issuance or transfer of up to the sum of the following: (i) 890,815 new shares, plus (ii) the number of shares of our common stock subject to outstanding grants under our 2011 Stock Incentive Plan as of the effective date of the 2015 Omnibus Plan, plus (iii) the number of shares of our common stock remaining available for issuance under the 2011 Stock Incentive Plan but not subject to previously exercised or paid grants as of the effective date of the 2015 Omnibus Plan. During the term of our 2015 Omnibus Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, beginning in calendar year 2016, by an amount equal 3% of the total number of outstanding shares of common stock on the last trading day in December of the prior calendar year.

If any options or stock appreciation rights, including outstanding options and stock appreciation rights granted under our 2011 Stock Incentive Plan, terminate, expire or are canceled, forfeited, exchanged or surrendered without having been exercised or if any stock awards, stock units or other stock-based awards, including outstanding awards granted under our 2011 Stock Incentive Plan, are forfeited, terminated or otherwise not paid in full, the shares subject to such grants will again be available for purposes of our 2015 Omnibus Plan. In addition, if any shares of our common stock are surrendered in payment of the exercise price of an option or stock appreciation right, the number of shares available for issuance under our 2015 Omnibus Plan will be reduced only by the net number of shares actually issued upon exercise and not by the total number of shares under which such option or stock appreciation right is exercised. If shares of our common stock are withheld in satisfaction of the withholding taxes incurred in connection with the issuance, vesting or exercise of any grant or the issuance of our common stock, then the number of shares of our common stock available for issuance under our 2015 Omnibus Plan shall be reduced by the net number of shares issued, vested or exercised under such grant. If any grants are paid in cash, and not in shares of our common stock, any shares of our common stock subject to such grants will also be available for future grants.

With respect to grants that are intended to meet the requirements for "qualified performance-based compensation" under Section 162(m) of the Internal Revenue Code, our 2015 Omnibus Plan contains the following annual limits, subject to adjustment as described in our 2015 Omnibus Plan:

- the maximum number of shares of our common stock for which grants measured in shares may be awarded to any employee in any calendar year shall not exceed 500,000 shares;
- the maximum dollar amount for which grants measured in cash dollars (other than bonus awards) that may be awarded to any employee in any calendar year shall not exceed \$3,500,000;
- the maximum aggregate amount of dividends and dividend equivalents that an employee may accrue in any calendar year shall not exceed \$35,000; and
- the maximum dollar amount that may be paid to an employee under bonus awards with respect to each 12-month period within a performance period shall not exceed \$500,000 in the aggregate.

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The 2015 Omnibus Plan also limits awards to non-employee directors during any calendar year to 300,000 shares of our common stock, subject to adjustment as described in our 2015 Omnibus Plan.

### *Adjustments*

In connection with stock splits, stock dividends, recapitalizations and certain other events affecting our common stock, our compensation committee will make adjustments as it deems appropriate in the maximum number of shares of common stock reserved for issuance as grants, the maximum number of shares of common stock that any individual participating in our 2015 Omnibus Plan may be granted in any year, the number and kind of shares covered by outstanding grants, the kind of shares that may be issued or transferred under our 2015 Omnibus Plan, the price per share or market value of any outstanding grants, the exercise price of options, the base amount of stock appreciation rights, the performance goals or other terms and conditions as our compensation committee deems appropriate.

### *Eligibility*

All of our employees are eligible to receive grants under our 2015 Omnibus Plan. In addition, our non-employee directors and key advisors who perform services for us may receive grants under our 2015 Omnibus Plan.

### *Vesting*

Our compensation committee determines the vesting of awards granted under our 2015 Omnibus Plan.

### *Options*

Under our 2015 Omnibus Plan, our compensation committee will determine the exercise price of the options granted and may grant options to purchase shares of common stock in such amounts as it determines. Our compensation committee may grant options that are intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code, or non-qualified stock options, which are not intended to so qualify. Incentive stock options may only be granted to our employees. Anyone eligible to participate in our 2015 Omnibus Plan may receive a grant of non-qualified stock options. The exercise price of a stock option granted under our 2015 Omnibus Plan cannot be less than the fair market value of a share of our common stock on the date the option is granted. If an incentive stock option is granted to a 10% stockholder, the exercise price cannot be less than 110% of the fair market value of a share of our common stock on the date the option is granted. The exercise price for any option is generally payable in cash; in certain circumstances as permitted by our compensation committee, by the surrender of shares of our common stock with an aggregate fair market value on the date the option is exercised equal to the exercise price; by payment through a broker in accordance with procedures established by the Federal Reserve Board; by surrender of the vested portion of the option to us for an appreciation distribution payable in shares of our common stock with a fair market value at the time of the option surrender equal to the dollar amount by which the then fair market value of the shares of our common stock subject to the surrendered portion exceeds the aggregate exercise price. The term of an option cannot exceed ten years from the date of grant, except that if an incentive stock option is granted to a 10% stockholder, the term cannot exceed five years from the date of grant.

Except as provided in the grant instrument, an option may only be exercised while a participant is employed by or providing service to us. Our compensation committee will determine in the grant instrument under what circumstances and during what time periods a participant may exercise an option after termination of employment,



*Stock Appreciation Rights*

Under our 2015 Omnibus Plan, our compensation committee may grant stock appreciation rights, which may be granted separately or in tandem with any option. Stock appreciation rights granted with a non-qualified stock option may be granted either at the time the non-qualified stock option is granted or any time thereafter while the option remains outstanding. Stock appreciation rights granted with an incentive stock option may be granted only at the time the grant of the incentive stock option is made. Our compensation committee will establish the base amount of the stock appreciation right at the time the stock appreciation right is granted, which will be equal to or greater than the fair market value of a share of our common stock as of the date of grant. If a stock appreciation right is granted in tandem with an option, the number of stock appreciation rights that are exercisable during a specified period will not exceed the number of shares of our common stock that the participant may purchase upon exercising the related option during such period. Upon exercising the related option, the related stock appreciation rights will terminate, and upon the exercise of a stock appreciation right, the related option will terminate to the extent of an equal number of shares of our common stock. A stock appreciation right is exercisable during the period specified in the grant instrument and is subject to vesting and other restrictions as specified in the grant instrument. Our compensation committee may accelerate the exercisability of any or all outstanding stock appreciation rights at any time for any reason. Generally, stock appreciation rights may only be exercised while the participant is employed by, or providing services to, us. When a participant exercises a stock appreciation right, the participant will receive the excess of the fair market value of the underlying common stock over the base amount of the stock appreciation right. The appreciation of a stock appreciation right will be paid in shares of our common stock, cash or both. The term of a stock appreciation right cannot exceed ten years from the date of grant.

*Stock Awards*

Under our 2015 Omnibus Plan, our compensation committee may grant stock awards. A stock award is an award of our common stock that may be subject to restrictions as our compensation committee determines. The restrictions, if any, may lapse over a specified period of employment or based on the satisfaction of pre-established criteria, in installments or otherwise, as our compensation committee may determine. Except to the extent restricted under the grant instrument relating to the stock award, a participant will have all of the rights of a stockholder as to those shares, including the right to vote and the right to receive dividends or distributions on the shares. Dividends with respect to stock awards that vest based on performance shall vest if and to the extent that the underlying stock award vests, as determined by our compensation committee. All unvested stock awards are forfeited if the participant's employment or service is terminated for any reason, unless our compensation committee determines otherwise.

*Stock Units*

Under our 2015 Omnibus Plan, our compensation committee may grant stock units to anyone eligible to participate in our 2015 Omnibus Plan. Stock units are phantom units that represent shares of our common stock. Stock units become payable on terms and conditions determined by our compensation committee and will be payable in cash or shares of our stock as determined by our compensation committee. All unvested stock units are forfeited if the participant's employment or service is terminated for any reason, unless our compensation committee determines otherwise.

*Bonus Awards*

Under the 2015 Omnibus Plan, our compensation committee may grant cash bonus awards to our employees who are executives or other key employees. Our compensation committee will determine which employees will receive bonus awards and the terms and conditions applicable to each bonus award, including the criteria for vesting.

*Other Stock-Based Awards*

Under our 2015 Omnibus Plan, our compensation committee may grant other types of awards that are based on, measured by or payable to anyone eligible to participate in our 2015 Omnibus Plan in shares of our common stock. Our compensation committee will determine the terms and conditions of such awards. Other stock-based awards may be payable in cash, shares of our common stock or a combination of the two.

*Dividend Equivalents*

Under our 2015 Omnibus Plan, our compensation committee may grant dividend equivalents in connection with grants of stock units or other stock-based awards made under our 2015 Omnibus Plan. Dividend equivalents entitle the participant to receive amounts equal to ordinary dividends that are paid on the shares underlying a grant while the grant is outstanding. Our compensation committee will determine whether dividend equivalents will be paid currently or accrued as contingent cash obligations. Dividend equivalents may be paid in cash, in shares of our common stock or in a combination of the two. Our compensation committee will determine the terms and conditions of the dividend equivalent grants, including whether the grants are payable upon the achievement of specific performance goals. Dividend equivalents with respect to stock units or other stock-based awards that vest based on performance shall vest and be paid only if and to the extent that the underlying stock units or other stock-based awards vest and are paid as determined by our compensation committee.

*Qualified Performance-Based Compensation*

Our 2015 Omnibus Plan permits our compensation committee to impose performance goals that must be met with respect to grants of stock awards, stock units, other stock-based awards, bonus awards, and dividend equivalents that are intended to meet the exception for qualified performance-based compensation under Section 162(m) of the Internal Revenue Code, referred to herein as "qualified performance grants." Prior to or soon after the beginning of a performance period, our compensation committee will establish the performance goals that must be met, the applicable performance periods, the amounts to be paid if the performance goals are met and any other conditions. Our 2015 Omnibus Plan is intended to comply with the transition relief for purposes of Section 162(m) of the Internal Revenue Code, as more fully described below.

The performance goals, to the extent designed to meet the requirements of "qualified performance-based compensation" under Section 162(m) of the Internal Revenue Code, will be based on one or more of the following criteria: cash flow; earnings (including gross margin, earnings before interest and taxes, earnings before taxes, earnings before interest, taxes, depreciation, amortization and charges for stock-based compensation, earnings before interest, taxes, depreciation and amortization, and net earnings); earnings per share; growth in earnings or earnings per share; stock price; return on equity or average stockholder equity; total stockholder return or growth in total stockholder return either directly or in relation to a comparative group; return on capital; return on assets or net assets; revenue, growth in revenue or return on sales; income or net income; operating income, net operating income or net operating income after tax; operating profit or net operating profit; operating margin; return on operating revenue or return on operating profit; regulatory filings; regulatory approvals, litigation and regulatory resolution goals; other operational, regulatory or departmental objectives; budget comparisons; growth in stockholder value relative to established indexes, or another peer group or peer group index; development and implementation of strategic plans and/or organizational restructuring goals; development and implementation of risk and crisis management programs; improvement in workforce diversity; compliance requirements and compliance relief; safety goals; productivity goals; workforce management and succession planning goals; economic value added (including typical adjustments consistently applied from generally accepted accounting principles required to determine economic value added performance measures); measures of customer satisfaction, employee satisfaction or staff development; development or marketing collaborations,

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formations of joint ventures or partnerships or the completion of other similar transactions intended to enhance the company's revenue or profitability or enhance its customer base; merger and acquisitions; and other similar criteria consistent with the foregoing.

### *Change of Control*

If we experience a change of control where we are not the surviving corporation (or survive only as a subsidiary of another corporation), unless our compensation committee determines otherwise, all outstanding grants that are not exercised or paid at the time of the change of control will be assumed by, or replaced with grants that have comparable terms by, the surviving corporation (or a parent or subsidiary of the surviving corporation).

Unless a grant instrument provides otherwise, if a participant's employment is terminated by the surviving corporation without cause upon or within 12 months following a change of control, the participant's outstanding grants will fully vest as of the date of termination; provided that if the vesting of any grants is based, in whole or in part, on performance, the applicable grant instrument will specify how the portion of the grant that becomes vested upon a termination following a change in control will be calculated.

If there is a change of control and all outstanding grants are not assumed by, or replaced with grants that have comparable terms by, the surviving corporation, our compensation committee may take any of the following action without the consent of any participant:

- determine that outstanding options and stock appreciation rights will accelerate and become fully exercisable and the restrictions and conditions on outstanding stock awards, stock units, bonus awards, and dividend equivalents immediately lapse;
- pay participants, in an amount and form determined by our compensation committee, in settlement of outstanding stock units, bonus awards, or dividend equivalents;
- require that participants surrender their outstanding stock options and stock appreciation rights in exchange for a payment by the company, in cash or shares of our common stock, equal to the difference between the exercise price and the fair market value of the underlying shares of common stock; provided, however, if the per share fair market value of the common stock does not exceed the per share stock option exercise price or stock appreciation right base amount, as applicable, the company will not be required to make any payment to the participant upon surrender of the stock option or stock appreciation right; or
- after giving participants an opportunity to exercise all of their outstanding stock options and stock appreciation rights, terminate any unexercised stock options and stock appreciation rights on the date determined by our compensation committee.

In general terms, a change of control under our 2015 Omnibus Plan occurs if:

- a person, entity or affiliated group, with certain exceptions, acquires more than 50% of our then outstanding voting securities;
- we merge into another entity unless the holders of our voting shares immediately prior to the merger have at least 50% of the combined voting power of the securities in the merged entity or its parent;
- we merge into another entity and the members of the board of directors prior to the merger would not constitute a majority of the board of the merged entity or its parent;
- we sell or dispose of all or substantially all of our assets;
- we are liquidated or dissolved; or

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- a majority of the members of our board of directors is replaced during any 12-month period or less by directors whose appointment or election is not endorsed by a majority of the incumbent directors.

### *Deferrals*

Our compensation committee may permit or require participants to defer receipt of the payment of cash or the delivery of shares of common stock that would otherwise be due to the participant in connection with a grant under our 2015 Omnibus Plan. Our compensation committee will establish the rules and procedures applicable to any such deferrals, consistent with the requirements of Section 409A of the Internal Revenue Code.

### *Withholding*

All grants under the Plan are subject to applicable United States federal (including FICA), state and local, foreign country or other tax withholding requirements. We may require that participants or other persons receiving grants or exercising grants to pay an amount sufficient to satisfy such tax withholding requirements with respect to such grants, or we may deduct from other wages and compensation paid by us the amount of any withholding taxes due with respect to such grant.

Our compensation committee may permit or require that our tax withholding obligation with respect to grants paid in our common stock to be paid by having shares withheld up to an amount that does not exceed the participant's minimum applicable withholding tax rate for United States federal (including FICA), state and local tax liabilities, or as otherwise determined by our compensation committee. In addition, our compensation committee may, in its discretion, and subject to such rules as the compensation committee may adopt, allow participants to elect to have such share withholding applied to all or a portion of the tax withholding obligation arising in connection with any particular grant.

### *No Repricing*

Except in connection with a corporate transaction involving the company (including, without limitation, any stock dividend, distribution (whether in the form of cash, our common stock, other securities or property), stock split, extraordinary cash dividend, recapitalization, change in control, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of shares of our common stock or other securities, or similar transactions), the Company may not, without obtaining stockholder approval, (i) amend the terms of outstanding options or stock appreciation rights to reduce the exercise price of such outstanding options or base price of such stock appreciation rights, (ii) cancel outstanding options or stock appreciation rights in exchange for options or stock appreciation rights with an exercise price or base price, as applicable, that is less than the exercise price or base price of the original options or stock appreciation rights or (iii) cancel outstanding options or stock appreciation rights with an exercise price or base price, as applicable, above the current stock price in exchange for cash or other securities.

### *Transferability*

Except as permitted by our compensation committee with respect to non-qualified stock options, only a participant may exercise rights under a grant during the participant's lifetime. Upon death, the personal representative or other person entitled to succeed to the rights of the participant may exercise such rights. A participant cannot transfer those rights except by will or by the laws of descent and distribution or, with respect to grants other than incentive stock options, pursuant to a domestic relations order. Our compensation committee may provide in a grant instrument that a participant may transfer non-qualified stock options to family members, or one or more trusts or other entities for the benefit or owned by family members, consistent with applicable securities laws.

*Amendment; Termination*

Our board of directors may amend or terminate our 2015 Omnibus Plan at any time, except that our stockholders must approve an amendment if such approval is required in order to comply with the Internal Revenue Code, applicable laws, or applicable stock exchange requirements. Unless terminated sooner by our board or extended with stockholder approval, our 2015 Omnibus Plan will terminate on the day immediately preceding the tenth anniversary of the date on which the underwriting agreement related to this offering is signed.

*Stockholder Approval*

The 2015 Omnibus Plan is intended to comply with the transition relief set forth in Treasury Regulation §1.162-27(f)(1) for companies that become publicly held in connection with an initial public offering. Following the transition period set forth therein, if grants are made as "qualified performance-based compensation", the 2015 Omnibus Plan must be reapproved by our stockholders no later than the first stockholders meeting that occurs after the close of the third calendar year following the calendar year in which the initial public offering occurs, and reapproved by our stockholders no later than the first stockholders meeting that occurs in the fifth year following such stockholder approval, if required by Section 162(m) of the Internal Revenue Code or the regulations thereunder.

*Establishment of Sub-Plans*

Our board of directors may, from time to time, establish one or more sub-plans under the 2015 Omnibus Plan to satisfy applicable blue sky, securities, or tax laws of various jurisdictions. Our board may establish such sub-plans by adopting supplements to the 2015 Omnibus Plan setting forth limitations on the compensation committee's discretion and such additional terms and conditions not otherwise inconsistent with the 2015 Omnibus Plan, as our board of directors will deem necessary or desirable. All such supplements will be deemed part of the 2015 Omnibus Plan, but each supplement will only apply to participants within the affected jurisdiction.

*Clawback*

Subject to applicable law, our compensation committee may provide in any grant instrument that if a participant breaches any restrictive covenant agreement between the participant and us, or otherwise engages in activities that constitute cause (as defined in our 2015 Omnibus Plan) either while employed by, or providing services to, us or within a specified period of time thereafter, all grants held by the participant will terminate, and we may rescind any exercise of an option or stock appreciation right and the vesting of any other grant and delivery of shares upon such exercise or vesting, as applicable on such terms as our compensation committee will determine, including the right to require that in the event of any rescission:

- the participant must return the shares received upon the exercise of any option or stock appreciation right and/or the vesting and payment of any other grants; or
- if the participant no longer owns the shares, the participant must pay to us the amount of any gain realized or payment received as a result of any sale or other disposition of the shares (if the participant transferred the shares by gift or without consideration, then the fair market value of the share on the date of the breach of the restrictive covenant agreement or activity constituting cause), net of the price originally paid by the participant for the shares.

Our compensation committee may also provide for clawbacks pursuant to the applicable clawback policy, which may be amended from time to time, adopted by our board of directors. Payment by the participant will be made in such manner and on such terms and conditions as may be required by our compensation committee. We will be entitled to set off against the amount of any such payment any amounts that we otherwise owe to the participant.

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Our compensation committee and board of directors approved grants of nonqualified stock options under our 2015 Omnibus Plan to each of our named executive officers that become effective upon the closing of this offering with an exercise price equal to the initial public offering price. These time-based option grants vest based upon continued employment or service over a four-year period with 25% vesting on the first anniversary of the date of grant and the balance vesting in 36 substantially equal monthly installments thereafter. The number of shares of common stock underlying the options granted to our named executive officers in connection with this offering are set forth in the table below:

<u>Name</u>	<u>Shares Underlying Time-Based Options</u>
Blake Paterson	160,000
John Kaiser	40,000

**401(k) Plan**

Our named executive officers participate in our broad-based 401(k) savings plan offered to all full time employees of the company. There is no mandatory matching or other employer contribution provided by the company during the year. Annually, the benefits committee determines if a discretionary match or other discretionary employer contribution is to be made. If made, any discretionary match or other employer contribution will vest over a six-year graded vesting schedule so that 20% vests each year of service. Vesting is accelerated upon death, disability and termination of the plan. Employees can designate the investment of their 401(k) accounts from among a broad range of mutual funds. We do not allow investment in our common stock through the 401(k) plan.

**Limitation of Liability and Indemnification**

Our amended and restated certificate of incorporation, which will become effective upon the closing of this offering, limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for voting or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the Delaware General Corporation Law is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the Delaware General Corporation Law.

In addition, our amended and restated certificate of incorporation, which will become effective upon the closing of this offering, provides that we are authorized indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we expect to enter into indemnification agreements with each of our current directors, officers, and some employees before the completion of this offering. These agreements provide for the indemnification of our directors, officers, and some employees for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were our agents. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors, officers and employees.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into indemnification agreements with all of our directors prior to the closing of this offering. These indemnification agreements may require us, among other things, to indemnify each such director and executive officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him in any action or proceeding arising out of his or her service as one of our directors or executive officers.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### **Non-Employee Director Compensation**

The following table sets forth information regarding the total compensation paid to our current non-employee directors during 2014 for their service on our board of directors. The compensation amounts presented in the table below are historical and are not indicative of the amounts we may pay our directors in the future. Directors who are also our employees receive no additional compensation for their services as directors and are not set forth in the table below. After consultation with Radford, our compensation consultant, our board of directors has approved a compensation policy for our non-employee directors that becomes effective upon the closing of this offering. This policy provides for the following compensation to our non-employee directors following this offering:

- The chair of our board of directors will receive an annual fee from us of \$60,000 and each other non-employee director will receive \$35,000;
- The chair of our audit committee will receive an annual fee from us of \$15,000 and each other members will receive \$7,500;
- The chair of our compensation committee will receive an annual fee from us of \$10,000 and each other members will receive \$5,000;
- The chair of our nominating and corporate governance committee will receive an annual fee from us of \$7,000 and each other members will receive \$3,500; and
- Each non-employee director will be entitled to an initial grant of options to purchase 16,714 shares of our common stock and an annual grant of options to purchase 8,357 shares of our common stock under our 2015 Plan. The initial grant will vest in three substantially equal annual installments over three years and the annual grant will vest in full or the one year anniversary of the grant date, in each case, subject to continued service from the date of grant until the applicable vesting dates.

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All fees under the director compensation policy will be on a rolling annual basis and no per meeting fees will be paid. We will also reimburse non-employee directors for reasonable expenses incurred in connection with attending board of director and committee meetings.

Name	Fees Earned or Paid in Cash	Total (\$)
Sol Barer, Ph.D.(1)	\$ 49,250	\$ 49,250
James Barrett, Ph.D.(2)(5)	—	—
Eugene A. Bauer, M.D.	40,500	40,500
Isaac Blech	44,500	44,500
Luke Evin, Ph.D.(2)(3)	—	—
John Catsimatidis(4)	—	—
Magnus Persson, M.D., Ph.D.	38,000	38,000
Behshad Sheldon(2)	—	—
Cary W. Sucoff(4)	35,500	35,500
Mayukh Sukhatme M.D.(2)(6)	—	—
Frank Torti, M.D.(2)(5)	—	—

- (1) Dr. Barer resigned from our board of directors on April 23, 2015.
- (2) Dr. Barrett, Dr. Evin, Ms. Sheldon, Dr. Sukhatme and Dr. Torti were each appointed to our board of directors on July 11, 2014.
- (3) Dr. Evin resigned from our board of directors on April 22, 2015.
- (4) Mr. Catsimatidis and Mr. Sucoff resigned from our board of directors on July 11, 2014.
- (5) Dr. Torti and Mr. Barrett resigned from our board of directors on June 26, 2015.
- (6) Dr. Sukhatme resigned from our board of directors on August 12, 2015.

*Uli Hacksell, Ph.D.*

On May 22, 2015, Dr. Hacksell was appointed to serve as the Chairman of our board of directors. In connection with his election to our board of directors, Dr. Hacksell was granted an option under our 2011 Stock Incentive Plan to purchase 11,607 shares of our common stock at an exercise price per share of \$6.13. Such option was fully vested on the date of grant. Also in connection with Dr. Hacksell's appointment, Dr. Hacksell became entitled to receive an annual cash retainer of \$35,000, paid quarterly in advance. Such retainer will be replaced by the retainer that will otherwise become payable to him under the non-employee director compensation policy to be implemented in connection with this offering.

**Non-Employee Director Equity Outstanding at 2014 Fiscal Year End**

The following table provides information about outstanding stock options and stock awards held by each of our non-employee directors as of December 31, 2014. All of these options and awards were granted under our 2011 Stock Incentive Plan.

	Option Awards Number of Securities Underlying Unexercised Options (#) Exercisable
Sol Barer, Ph.D.(1)	98,214
James Barrett, Ph.D.(2)	—



	<u>Option Awards</u>
	<u>Number of Securities</u>
	<u>Underlying Unexercised</u>
	<u>Options (#)</u>
	<u>Exercisable</u>
Eugene A. Bauer, M.D.	7,142
Isaac Blech	46,428
Luke Evin, Ph.D.(3)	—
Magnus Persson, M.D., Ph.D.	19,047
Behshad Sheldon	—
Mayukh Sukhatme M.D.(4)	—
Frank Torti, M.D.(2)	—

- (1) Dr. Barer resigned from our board of directors on April 23, 2015.
- (2) Dr. Torti and Mr. Barrett resigned from our board of directors on June 26, 2015.
- (3) Dr. Evin resigned from our board of directors on April 22, 2015.
- (4) Dr. Sukhatme resigned from our board of directors on August 12, 2015.

## TRANSACTIONS WITH RELATED PERSONS

The following is a description of transactions since January 1, 2012 to which we have been a party, and in which any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, or affiliates or immediate family members of any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, had or will have a direct or indirect material interest. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, from unrelated third parties.

### Convertible Preferred Stock Financings

From July 2014 through September 2014, we entered into a Series B Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors at a purchase price of \$0.2999 per share an aggregate of 58,948,735 shares of Series B convertible preferred stock. The aggregate consideration for the Series B convertible preferred stock offering was \$15.0 million in cash and \$2.3 million in aggregate principal and interest due under convertible promissory notes and demand promissory notes. The following table sets forth the shares of Series B convertible preferred stock issued to our directors, executive officers and holders of more than five percent of our capital stock and their affiliates, and the breakdown of the purchase price paid by such persons:

Name	Shares of Series B Convertible Preferred Stock Purchased	Purchase Price for Series B Preferred Stock	
		Paid in Cash	Financed by Amounts Due under Existing Convertible Notes
<b>Directors:</b>			
Sol Barer, Ph.D.(1)	893,517	—	\$ 200,970
<b>5% Stockholders:</b>			
New Enterprise Associates 14, L.P. and affiliates	16,672,224	\$ 4,666,667	\$ 333,333
Apple Tree Partners IV, LP	16,672,224	\$ 4,666,667	\$ 333,333
MPM BioVentures V, LP and affiliates	16,672,224	\$ 4,667,000	\$ 333,000

(1) Dr. Barer resigned from our board of directors on April 23, 2015.

In August 2013, we entered into a Series A-1 Preferred Stock and Warrant Purchase Agreement pursuant to which we issued and sold to investors at a purchase price of \$0.75 per unit an aggregate of 9,074,511 shares of Series A-1 convertible preferred stock and warrants to purchase 81,020 shares of our common stock at \$28.00 per share which is subject to adjustment as set forth in such warrant. The aggregate consideration for the Series A-1 convertible preferred stock offering was \$6.8 million in cash. The following table sets forth the shares of Series A-1 convertible preferred stock and warrants issued

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to our directors, executive officers and holders of more than five percent of our capital stock and their affiliates, and the breakdown of the purchase price paid:

<u>Name</u>	<u>Shares of Series A-1 Convertible Preferred Stock Purchased</u>	<u>Shares of Common Stock Issuable Upon Exercise of Warrants</u>	<u>Aggregate Purchase Price</u>
<b>Directors:</b>			
Sol Barer, Ph.D.(1)	53,334	476	\$ 40,000

- (1) Dr. Barer resigned from our board of directors on April 23, 2015.

From February 2012 through May 2012, we entered into Series A Preferred Stock and Warrant Purchase Agreements pursuant to which we issued and sold to investors at a purchase price of \$0.75 per unit an aggregate of 31,116,391 shares of Series A convertible preferred stock and warrants to purchase 277,824 shares of our common stock at \$28.00 per share. The aggregate consideration for the Series A convertible preferred stock offering was \$20.3 million in cash and \$3.1 million in aggregate principal and interest due under a convertible demand promissory note held by an affiliate of Mr. Blech, a member of our board of directors, which pursuant to the terms of such note, was converted into shares of Series A convertible preferred stock. In addition, for any investor of Series A convertible preferred stock who also participated in the Series A-1 convertible preferred stock offering, we amended the terms of the original warrants issued in connection with such Series A convertible preferred stock by reducing the exercise price of the warrants issued from \$28.00 per share of common stock to \$14.00 per share of common stock provided that such investor purchased a minimum of 40% of their original Series A convertible preferred stock investment. The following table sets forth the shares of Series A convertible preferred stock and warrants issued to our directors, executive officers and holders of more than five percent of our capital stock and their affiliates, and the breakdown of the purchase price paid:

<u>Name</u>	<u>Shares of Series A Convertible Preferred Stock Purchased</u>	<u>Shares of Common Stock Issuable Upon Exercise of Warrants</u>	<u>Aggregate Purchase Price</u>
<b>Directors:</b>			
Sol Barer, Ph.D.(1)	133,333	1,190	\$ 100,000
Isaac Blech(2)	4,210,808	37,596	\$ 3,158,106
John Catsimatidis(3)	400,000	3,571	\$ 300,000

- (1) Dr. Barer resigned from our board of directors on April 23, 2015.
- (2) These numbers include the (i) 4,077,475 shares of Series A convertible preferred stock held by Daniel Blech Trust DTD 8/3/2005, or the Blech Trust, and (ii) 36,406 common shares issuable upon the exercise of warrants held by the Blech Trust. Mr. Blech has voting control over the shares held by the Blech Trust.
- (3) Represents Series A convertible preferred stock and warrants held by United Acquisition Corp., which is indirectly 100% owned and controlled by Mr. Catsimatidis. Mr. Catsimatidis resigned from our board of directors on July 11, 2014.

### Loan Transaction

In July 2014, we sold approximately \$1.0 million in gross principal amount of convertible demand promissory notes to the Series B convertible preferred stock venture capital investors. The note carried

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interest at a rate of 0.31% per annum, compounded annually. In July 2014, pursuant to the terms of the notes, all principal and interest due under the notes was converted into shares of Series B preferred stock. The following table sets forth the amount of notes purchased by our directors, executive officers and holders of more than five percent of our capital stock and their affiliates:

<u>Name</u>	<u>Initial Principal Amount of Note</u>
<b>5% Stockholders:</b>	
New Enterprise Associates 14, L.P. and affiliates	\$ 333,333
Apple Tree Partners IV, LP	\$ 333,333
MPM BioVentures V, LP and affiliates	\$ 333,000

On each of April 29, 2014 and June 9, 2014, we executed a convertible demand promissory note for an aggregate principal amount of \$200,000 with Dr. Barer, a former member of our board of directors. The note carried interest at a rate of 6% per annum, compounded annually. On July 11, 2014, the principal outstanding under each convertible demand promissory note, plus all accrued and unpaid interest of \$970 in the aggregate, was converted into 893,517 shares of Series B convertible. In connection with issuing the convertible demand promissory notes, Dr. Barer received a warrant to purchase 23,817 shares of our common stock at an exercise price of \$8.40 per share.

**Offer Letters**

We currently have written offer letters with our President and Chief Executive Officer, Dr. Blake Paterson, and our Chief Business Officer, John Kaiser. For more information, refer to the section entitled "Executive Compensation—Offer Letters."

In addition, we have a written offer letter with the chairman of our board of directors, Uli Hacksell, Ph.D., and with our Chief Medical Officer and Head Regulatory Affairs, Ronald Marcus, M.D.

*Uli Hacksell, Ph.D.*

Dr. Hacksell entered into an offer letter effective May 20, 2015. The offer letter provides for an annual retainer of \$35,000 and a grant of a stock option to purchase up to 11,607 shares of our common stock to be issued under our 2011 Stock Incentive Plan. Dr. Hacksell will maintain the confidentiality of all of our confidential information obtained by him as a result of his serving as a director.

*Ronald Marcus, M.D.*

Dr. Marcus entered into an offer letter effective May 18, 2015. The offer letter provides for an annual base salary of \$310,000. Dr. Marcus was entitled to up to \$3,000 in relocation expenses and is entitled to up to \$2,000 per month for living expenses. The offer letter provides for an initial stock option grant of 55,714 shares of our common stock to be issued under our 2011 Stock Incentive Plan, subject to standard vesting terms so long as Dr. Marcus remains employed by us. In addition, Dr. Marcus is eligible to receive a discretionary annual bonus as determined by our board of directors or the compensation committee of our board of directors, in its sole discretion, provided that Dr. Marcus is employed by the company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid to executives of similar grade in similarly situated companies in the biotechnology industry, subject to corporate and individual performance.

Pursuant to the terms of Dr. Marcus's offer letter, if Dr. Marcus's employment is terminated for any reason, then the company will pay Dr. Marcus his base salary and expenses accrued, but unpaid as

of the date of his termination, and any benefits accrued and due under any applicable benefit plans and programs of the company.

If Dr. Marcus's employment is terminated without cause or by Dr. Marcus for good reason, provided he complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company, Dr. Marcus is entitled to an amount equal to the sum of (i) six months of his then-current base salary and (ii) full vesting of the options granted in accordance with the agreement. In addition, Dr. Marcus is entitled to company-paid COBRA premiums for 12 months or until he is eligible for substantially equal coverage.

The offer letter provides that at all times during Dr. Marcus's employment and thereafter, Dr. Marcus will maintain the confidentiality of all confidential information obtained by him as a result of his employment with the company, assign all inventions and not disparage the company or any of its officers, directors, employees, shareholders or products. In addition, during the term of Dr. Marcus's employment with the company, and for the 12 month period after Dr. Marcus's termination of employment, Dr. Marcus cannot (i) compete against the company, (ii) interfere with the relationships between the company and any of its subsidiaries, affiliates or any of their respective vendors or licensors, or (iii) recruit in any way the employees of the company.

*Mariam E. Morris CPA*

Mariam Morris entered into an offer letter with the company effective August 24, 2015. Beginning on the effective date, We agreed to pay a base salary at an annual rate of not less than \$277,900. The annual base salary may further increase from time to time. In connection with Ms. Morris' commencement of employment, she became entitled to reimbursement of temporary living expenses up to, but not exceeding, \$3,000 per month, for up to six months. We will also reimburse moving and related expenses to establish permanent residence in Baltimore, not to exceed \$20,000.

Ms. Morris will receive an option to purchase shares of our common stock. The option will be granted according to the guidelines to be set by our compensation committee and the 2015 Omnibus Plan. Beginning in 2016, Ms. Morris will be eligible to participate in the 2015 Omnibus Plan at an annual target set by our board of directors. Ms. Morris is eligible to receive a discretionary annual bonus as determined by our board of directors or our compensation committee, in its sole discretion, provided that Ms. Morris is employed on the date such annual bonus is paid. Such bonus may consist of cash and/or grants of additional equity awards in the company and is intended to be substantially consistent with cash bonuses and equity award bonuses paid to executives of similar grade in similarly situated companies in the biotechnology industry, subject to the operations and financial condition of the company and her level of individual performance. Ms. Morris' cash bonus target for 2015 will be 27.5% of her base salary, prorated based on the actual number of days she was employed during the fiscal year.

Pursuant to the terms of Ms. Morris' offer letter, if Ms. Morris' employment is terminated for any reason, then the company will pay Ms. Morris' her base salary, bonus, and expenses accrued, but unpaid as of the date of her termination, and any benefits accrued and due under any applicable benefit plans and programs of the company.

If Ms. Morris' employment is terminated without cause or by Ms. Morris for good reason, provided she complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company, Ms. Morris is entitled to an amount equal to the sum of (i) six months of her then current base salary and (ii) full vesting of the options granted in accordance with the agreement. In addition, Ms. Morris is entitled to company paid COBRA premiums for 12 months or until she is eligible for substantially equal coverage.

**Stock Options Granted to Executive Officers and Directors**

We have granted stock options under our 2011 Stock Incentive Plan and outside of such plan to our executive officers and directors. The table below summarizes the stock option grants made to such persons since January 1, 2012.

<u>Optionee Name</u>	<u>Grant Date</u>	<u>Price Per Share</u>	<u>Shares Issued</u>
Blake M. Paterson, M.D.	5/8/2012	\$ 8.68	107,142
Blake M. Paterson, M.D.	7/10/2014	\$ 16.80	54,353
Sharon Rowland, Ph.D.	5/8/2012	\$ 8.68	3,571
Sharon Rowland, Ph.D.	2/5/2013	\$ 8.68	3,571
Sharon Rowland, Ph.D.	7/10/2014	\$ 10.08	5,892
Reza Mazhari, Ph.D.	5/8/2012	\$ 8.68	7,142
Reza Mazhari, Ph.D.	2/5/2013	\$ 8.68	4,821
Reza Mazhari, Ph.D.	7/10/2014	\$ 10.08	8,214
Sol J. Barer, Ph.D.	1/10/2012	\$ 5.60	85,714
Sol J. Barer, Ph.D.	5/13/2014	\$ 10.08	12,500
James Vornov, M.D., Ph. D.	11/9/2012	\$ 8.68	14,285
James Vornov, M.D., Ph. D.	7/10/2014	\$ 10.08	16,071
John J. Kaiser	11/9/2012	\$ 8.68	14,285
John J. Kaiser	8/29/2013	\$ 8.96	7,142
John J. Kaiser	7/10/2014	\$ 10.08	19,285
Federica F. O'Brien	8/29/2013	\$ 8.96	26,785
Federica F. O'Brien	7/10/2014	\$ 10.08	7,142
Bernadine H. Fraser, Ph.D.	5/8/2012	\$ 8.68	1,785
Bernadine H. Fraser, Ph.D.	11/9/2012	\$ 8.68	892
Bernadine H. Fraser, Ph.D.	7/10/2014	\$ 10.08	2,678
Isaac Blech	5/8/2012	\$ 8.68	53,571
Isaac Blech	5/13/2014	\$ 10.08	10,714
Cary W. Sucoff	5/8/2012	\$ 8.68	7,142
Cary W. Sucoff	5/13/2014	\$ 10.08	7,142
Dr. Eugene Bauer, M.D.	5/13/2014	\$ 10.08	7,142
Magnus Persson, M.D., Ph. D.	5/13/2014	\$ 10.08	7,142
Magnus Persson, M.D., Ph. D.	7/10/2014	\$ 10.08	17,857
Ronald Marcus, M.D.	6/2/2015	\$ 6.13	55,714
Uli Hacksell, Ph. D.	6/2/2015	\$ 6.13	11,607
			<u>581,301</u>

- (1) Dr. Barer resigned from our board of directors on April 23, 2015.
- (2) Dr. Rowland resigned as our Vice President of Regulatory Affairs on April 3, 2015.
- (3) Dr. Mazhari resigned as our Vice President of Preclinical Development on March 2, 2015.
- (4) Dr. Vornov resigned as our Chief Medical Officer on January 9, 2015.
- (5) Ms. O'Brien resigned as our Chief Financial Officer on April 23, 2015.
- (6) Mr. Sucoff resigned from our board of directors on July 11, 2014.

For further information regarding stock option grants to our executive officers and directors, see the section entitled "Executive Compensation."

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In addition, in September 2014, we issued a warrant to purchase 2,380 shares of our common stock to Mr. Sucoff, a former member of our board of directors, at an exercise price of \$8.68 per share, in consideration for his past services to the Company.

### **Registration Rights**

We are a party to a Second Amended and Restated Investors' Rights Agreement with the holders of our convertible preferred stock, including some of our 5% stockholders and their affiliates and entities affiliated with our directors. This agreement provides these holders the right, subject to the terms of lock-ups entered into in connection with this offering, following the closing of this offering, to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

### **Indemnification Agreements**

We intend to enter into indemnification agreements with each of our directors and certain of our executive officers. These agreements will require us to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

### **Policies and Procedures for Related Person Transactions**

In connection with this offering, our board of directors plans to adopt a written related person transaction policy to set forth policies and procedures for the review and approval or ratification of related person transactions. Effective upon the closing of this offering, this policy is expected to cover any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we are, were or will be a participant, the amount involved exceeds \$120,000, with one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person".

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our audit committee. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the interests, direct or indirect, of any related person in the transaction;
- the purpose of the transaction;
- the proposed aggregate value of such transaction, or, in the case of indebtedness, that amount of principal that would be involved;
- the risks, costs and benefits to the company;
- the availability of other sources of comparable products or services;
- management's recommendation with respect to the proposed related person transaction;

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- the terms of the transaction;
- the availability of other sources for comparable services or products;
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

Our audit committee will approve only those related person transactions that, in light of known circumstances, are in, or are not inconsistent with, the best interests of the company and its stockholders, as the audit committee determines in the good faith exercise of its discretion.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- transactions involving compensation for services provided to the company as an employee, consultant or director; and
- a transaction, arrangement or relationship in which a related person's participation is solely due to the related person's position as a director of an entity that is participating in such transaction, arrangement or relationship.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it has been the practice of our board of directors to consider the nature of and business reason for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of the company, or not contrary to, our best interests. In addition, all related person transactions required prior approval, or later ratification, by our board of directors.



## PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of August 15, 2015 by:

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

The column entitled "Percentage of Shares Beneficially Owned—Before Offering" is based on a total of 4,630,143 shares of our common stock, which includes 649,721 shares of our common stock outstanding as of August 15, 2015 and 3,980,422 shares of our common stock issuable upon the automatic conversion of all outstanding shares of our convertible preferred stock. The column entitled "Percentage of Shares Beneficially Owned—After Offering" also gives effect to the issuance by us of 4,230,769 shares of our common stock in this offering. The percentage ownership information assumes no exercise of the underwriters' over-allotment option to purchase additional shares.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days after August 15, 2015 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to applicable community property laws, where applicable. Except as otherwise set forth below, the address of each beneficial owner is c/o Cerecor Inc., 400 E Pratt Street, Suite 606, Baltimore, Maryland 21202.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>5% Stockholders:</b>			
New Enterprise Associates 14, L.P. and affiliates(1) c/o new Enterprise Associates 1954 Greenspring Drive, Suite 600 Timonium, MD 21093	595,435	12.9%	6.7%
Apple Tree Partners IV, L.P.(2) 47 Hulfish Street, Suite 441 Princeton, NJ 08542	595,435	12.9%	6.7%
MPM BioVentures V, L.P. and affiliates(3) 200 Clarendon Street, 54th Floor Boston, MA 02116	595,435	12.9%	6.7%
<b>Directors and Named Executive Officers:</b>			
Blake M. Paterson, M.D.(4)	217,566	4.5%	2.4%
James Vornov, M.D., Ph.D.	—	—	—
John Kaiser(5)	33,569	*	*
Eugene A. Bauer, M.D.(6)	33,927	*	*
Isaac Blech(7)	487,363	10.3%	5.4%
Uli Hacksell, Ph.D.(8)	11,607	*	*
Magnus Persson, M.D., Ph.D.(9)	24,999	*	*
Phil Gutry	—	—	—
Behshad Sheldon	—	—	—
All current executive officers and directors as a group (11 persons)(10)	814,089	16.4%	8.8%

\* Less than one percent.

- (1) Consists of (a) 594,245 shares of common stock issuable upon the automatic conversion of 16,638,880 shares of Series B convertible preferred stock held by New Enterprise Associates 14, L.P., or NEA 14, and (b) 1,190 shares of common stock issuable upon the automatic conversion of 33,334 shares of Series B convertible preferred stock held by NEA Ventures 2014, L.P., or NEA Ventures. The shares directly held by NEA 14 are indirectly held by NEA Partners 14, Limited Partnership, or NEA Partners 14, the sole general partner of NEA 14, NEA 14 GP, LTD., or, NEA 14 GP, the sole general partner of NEA Partners 14, and each of the individual directors of NEA 14 GP. The individual directors of NEA 14 GP are M. James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Anthony A. Florence, Jr., Patrick J. Kerins, Krishna "Kittu" Kolluri, David M. Mott, Scott D. Sandell, Peter Sonsini, Ravi Viswanathan and Harry R. Weller. NEA 14, NEA Partners 14, NEA 14 GP and the directors of NEA GP share voting and dispositive power with respect to the shares held by NEA 14. The shares directly held by NEA Ventures are indirectly held by Karen P. Welsh, the general partner of NEA Ventures, who holds voting and dispositive power with respect to the shares held by NEA Ventures. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein, if any.

- (2) Consists of 595,435 shares of common stock issuable upon the automatic conversion of 16,672,224 shares of Series B convertible preferred stock held by Apple Tree Partners IV, L.P., or ATP IV. As the sole general partner of ATP IV, ATP III GP, Ltd., or the GP, may be deemed to own beneficially our shares held by ATP IV. As the sole director of the GP, Dr. Seth L. Harrison may be deemed to own beneficially our shares held by ATP IV. Dr. Harrison disclaims beneficial ownership except to the extent of his pecuniary interest in our shares held by ATP IV.
- (3) Consists of (a) 573,170 shares of common stock issuable upon the automatic conversion of 16,048,760 shares of Series B convertible preferred stock held by MPM BioVentures V, L.P., or MPM BioVentures V, and (b) 22,266 shares of common stock issuable upon the automatic conversion of 623,464 shares of Series B convertible preferred stock held by MPM Asset Management Investors BV5 LLC, or MPM Asset Management. MPM BioVentures V GP LLC is the general partner of MPM BioVentures V. MPM BioVentures V LLC is the managing member of MPM BioVentures V GP LLC and the manager of Asset Management LLC. The members of MPM BioVentures V LLC are Luke Evnin, Todd Foley, Ansbert Gadicke, Vaughn Kailian and James Scopa. Each member shares voting and dispositive power with respect to the shares held by each of MPM BioVentures V and MPM Asset Management. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein, if any.
- (4) Includes 161,495 shares of common stock issuable upon the exercise of options within 60 days of August 15, 2015.
- (5) Includes 33,569 shares of common stock issuable upon the exercise of options within 60 days of August 15, 2015.
- (6) Includes 7,142 shares of common stock issuable upon the exercise of options within 60 days of August 15, 2015.
- (7) Includes (i) 5,952 shares of common stock issuable upon the automatic conversion of 133,333 shares of Series A convertible preferred stock and 182,030 shares of common stock held by Daniel Blech Trust DTD 8/3/2005, or the Blech Trust, issuable upon the automatic conversion of 4,077,475 shares of Series A convertible preferred stock, (ii) 64,285 shares of common stock issuable upon the exercise of stock options within 60 days of August 15, 2015 and (iii) 1,190 shares of common stock issuable upon the exercise of warrants within 60 days of August 15, 2015 held by Mr. Blech 2015, and 36,406 shares of common stock issuable upon the exercise of warrants within 60 days of August 15, 2015 held by the Blech Trust. Mr. Blech has voting control over all of the shares held by the Blech Trust and Mr. Blech disclaims beneficial ownership of such shares.
- (8) Includes 11,607 shares of our common stock issuable upon the exercise of options within 60 days of August 15, 2015.
- (9) Includes 24,999 shares of common stock issuable upon the exercise of options within 60 days of August 15, 2015.
- (10) Includes (i) the number of shares beneficially owned by the directors and named executive officers listed in the above table, other than Dr. Vornov, whose employment with the company ended on January 9, 2015, (ii) 5,058 shares of common stock issuable upon the exercise of stock options within 60 days of August 15, 2015 held by Dr. Fraser and (iii) Dr. Marcus and Ms. Morris who currently do not beneficially own any shares of our common stock and do not have the right to acquire beneficial ownership of any shares of our common stock within 60 days of August 15, 2015.

## DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 200,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of undesignated preferred stock, par value \$0.001 per share. The following is a summary of the rights of our common and convertible preferred stock and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

### **Common Stock**

On June 30, 2015, there were (i) 649,721 shares of our common stock outstanding, held of record by 24 stockholders, (ii) 510,884 shares of our common stock subject to outstanding options, (iii) 490,756 shares of our common stock issuable upon the exercise of warrants which warrants are expected to remain outstanding upon the closing of this offering, (iv) 166,718 shares of our common stock issuable upon the exercise of warrants outstanding, which warrants will expire upon the closing of this offering in accordance with their terms, unless exercised prior thereto and (v) 22,328 shares of our common stock issuable upon the exercise of the warrant outstanding as of June 30, 2015, which warrant is exercisable to purchase shares of Series B convertible preferred stock prior to the completion of this offering and which warrant is expected to remain outstanding upon the closing of this offering.

Based on (i) 649,721 shares of our common stock outstanding as of June 30, 2015, (ii) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,980,422 shares of our common stock upon the closing of this offering, and (iii) the issuance of 4,230,769 shares of common stock in this offering, there will be 8,860,912 shares of our common stock outstanding upon the closing of this offering.

### ***Voting***

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

### ***Dividends***

Subject to preferences that may be applicable to any then outstanding convertible preferred stock, the holders of 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, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of convertible preferred stock.

### ***Rights and Preferences***

Holders of our common stock have no preemptive, conversion or subscription 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 our convertible preferred stock that we may designate and issue in the future.

### ***Fully Paid and Nonassessable***

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

### **Preferred Stock**

On June 30, 2015, there were 31,116,391 shares of Series A convertible preferred stock outstanding, held of record by 154 stockholders, 9,074,511 shares of Series A-1 convertible preferred stock outstanding, held of record by 146 stockholders, 58,948,735 of Series B convertible preferred stock, held of record by 15 stockholders. Pursuant to the terms of the convertible preferred stock, each share of Series A convertible preferred stock will automatically convert into 0.04464 shares of our common stock immediately prior to the closing of this offering, each share of Series A-1 convertible preferred stock will automatically convert into 0.05357 shares of our common stock immediately prior to the closing of this offering, and each share of Series B convertible preferred stock will automatically convert into 0.03571 share of our common stock immediately prior to the closing of this offering. Accordingly, immediately upon the closing of this offering, the outstanding shares of convertible preferred stock will automatically convert into an aggregate amount of 3,980,422 shares of our common stock. No fractional shares of our common stock will be issued upon the conversion of our preferred stock. In lieu of any fractional shares, we will pay a cash amount to the holder of such fractional share equal to the fair market value of such fractional share as determined by our board of directors.

Following this offering, under our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power, impair the liquidation rights of our common stock or otherwise adversely affect the rights of holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

### **Options**

As of June 30, 2015, options to purchase an aggregate of 510,884 shares of our common stock at a weighted average exercise price of \$8.88 per share were outstanding.

## Warrants

The following table summarizes the warrants to purchase an aggregate of 657,474 shares of our common stock outstanding as of June 30, 2015:

<u>Number of Warrants</u>	<u>Number of Holders</u>	<u>Per Share Exercise Price</u>	<u>Expiration Date</u>
109,976	43	\$ 28.00	February 2017
29,260	36	\$ 14.00	February 2017
90,529	45	\$ 28.00	March 2017
29,557	33	\$ 14.00	March 2017
130,233	2	\$ 28.00	April 2017
14,284	3	\$ 28.00	July 2017
80,966	149	\$ 28.00	August 2018
3,571	1	\$ 28.00	December 2018
59,542	3	\$ 8.40	April 2019
23,816	3	\$ 8.40	May 2019
65,497	3	\$ 8.40	June 2019
17,863	1	\$ 8.40	July 2019
2,380	1	\$ 8.68	May 2022

In addition, as of June 30, 2015, there is one warrant to purchase 625,208 shares of our Series B convertible preferred stock at an exercise price equal to \$0.2999 per share that is exercisable for five years following the closing of this offering. This warrant shall become, in accordance with its terms, a warrant to purchase 22,328 shares of common stock at an exercise price of \$8.40 per share upon the closing of this offering.

490,756 shares of our common stock issuable upon the exercise of certain of these warrants has a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Certain of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of stock dividends, stock splits and reclassifications, consolidations or combinations. 166,718 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2015 will expire upon the closing of this offering in accordance with their terms, unless exercised prior thereto. The table set forth above does not include a warrant to purchase 24,306 shares of our common stock, at an exercise price of \$21.00 per share, we issued to Maxim Partners LLC, or Maxim, on August 23, 2013. On June 12, 2015, we entered into an agreement with Maxim to terminate the warrant effectively immediately without any consideration due to Maxim.

The holders of certain of these warrants are entitled to registration rights under our Second Amended and Restated Investors' Rights Agreement, as described in more detail under "—Registration Rights."

## Registration Rights

Under our Second Amended and Restated Investors' Rights Agreement, upon the closing of this, holders of a total of 5,143,229 shares of our common stock that will be outstanding after this offering, which includes shares of common stock issuable upon exercise of outstanding warrants, will have certain registration rights. The registration rights are described below.

### ***Demand Registration Rights***

At any time after 180 days after the closing of this offering, the holders of a majority of the shares then outstanding having demand registration rights may request that we register all or a portion of their shares of common stock for sale under the Securities Act. We will effect the registration as requested so long as the aggregate price to the public, net of expenses, in connection with any such offering is at least \$10.0 million unless, in the good faith judgment of our board of directors, such registration would be materially detrimental to the company and its stockholders and should be delayed. We are not obligated to file a registration statement pursuant to this provision on more than two occasions.

In addition, when we are eligible for the use of Form S-3, or any successor form, holders having demand registration rights may make requests that we register all or a portion of their common stock for sale under the Securities Act on Form S-3, or any successor form, so long as the aggregate price to the public, net of expenses, in connection with any such offering is at least \$1.0 million unless, in the good faith judgment of our board of directors, such registration would be materially detrimental to the company and its stockholders and should be delayed. We are not obligated to file a Form S-3 pursuant to this provision on more than two occasions in any 12-month period.

### ***Incidental Registration Rights***

In addition, if at any time after this offering we register any shares of our common stock for public sale, the holders of all shares having piggyback registration rights are entitled to notice of the registration and to include all or a portion of their shares of common stock in the registration.

### ***Other Provisions***

In the event that any registration in which the holders of registrable shares participate pursuant to the Second Amended and Restated Investors' Rights Agreement is an underwritten public offering, the number of registrable shares to be included may, in specified circumstances, be limited due to market conditions.

We will pay all registration expenses, other than underwriting discounts and selling commissions, and the reasonable fees and expenses of a single special counsel for the selling stockholders, related to any demand, piggyback and Form S-3 registration. The Second Amended and Restated Investors' Rights Agreement contains customary cross-indemnification provisions, pursuant to which we must indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us, and they must indemnify us for material misstatements or omissions in the registration statement attributable to them. The demand, piggyback and Form S-3 registration rights described above will expire upon the earlier of (i) the later of five years from the closing of this offering and August 23, 2020, (ii) a holder holds less than one percent of all securities subject to registration rights and the holder may sell all registrable securities pursuant to Rule 144 without restrictions during any three-months period or (iii) the closing of a Deemed Liquidation Event, as such term is defined in our amended and restated certificate of incorporation as in effect prior to the closing of this offering.

### ***Anti-Takeover Effects of Delaware Law and Our Charter and Bylaws***

Provisions of Delaware law and our certificate of incorporation and by-laws could make it more difficult to acquire us by means of a tender offer, a proxy contest, open market purchases, removal of incumbent directors and otherwise. These provisions, summarized below, are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. 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 takeover or acquisition proposals because negotiation of these proposals could result in an improvement of their terms.

***Delaware Anti-Takeover Law***

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least  $66\frac{2}{3}\%$  of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

The existence of this provision generally will have an anti-takeover effect for transactions not approved in advance by the board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

***Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws***

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or



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transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least  $66\frac{2}{3}\%$  of our then outstanding common stock.

### **NASDAQ Capital Market Listing**

Our common stock was approved for listing on the NASDAQ Capital Market under the symbol "CERC."

### **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 15<sup>th</sup> Avenue Brooklyn, NY 11219.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market for our common stock existed, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options and warrants, or the anticipation of such sales, could adversely affect prevailing market prices of our common stock from time to time and could impair our ability to raise equity capital in the future. Furthermore, because only a limited number of shares of our common stock will be available for sale shortly after this offering due to certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after such restrictions lapse, or the anticipation of such sales, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future. Our common stock was approved for listing on the NASDAQ Capital Market under the symbol "CERC."

Upon the closing of this offering, we will have outstanding 8,860,912 shares of our common stock, after giving effect to the issuance of 4,230,769 shares of our common stock in this offering and the automatic conversion of all outstanding shares of our convertible preferred stock. The number of shares outstanding upon the closing of this offering assumes no exercise of outstanding options or warrants.

All of the shares sold in this offering will be freely tradable unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. The remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements as described below. Following the expiration of the lock-up period, all shares will be eligible for resale, subject to compliance with Rule 144 or Rule 701 of the Securities Act, to the extent these shares have been released from any repurchase option that we may hold.

Subject to the lock-up agreements, described in the section entitled "Underwriting—Lock-Up Agreements," we may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, 2,169,019 shares of common stock that are either subject to outstanding options or warrants or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements or other similar contractual commitments restricting the sale of such shares and Rule 144 and Rule 701 of the Securities Act.

### **Rule 144**

In general, under Rule 144 of the Securities Act, as in effect on the date of this prospectus, beginning 90 days after the date of this prospectus, any person who is not our affiliate at any time during the preceding three months, and who has beneficially owned their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares of our common stock provided current public information about us is available, and, after owning such shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares of our common stock without restriction.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months, and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our

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affiliates, is entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares, or shares if the underwriters exercise their over-allotment option in full, immediately following this offering, based on the number of shares of our common stock outstanding upon the closing of this offering; or
- the average weekly trading volume of our common stock on NASDAQ during the four calendar weeks preceding the filing of a Notice of Proposed Sale of Securities pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon expiration of the 180-day lock-up period described below and other similar contractual restrictions 4,630,143 shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

### **Rule 701**

In general, under Rule 701 of the Securities Act, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act, is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

### **Lock-up Agreements**

As described under the section entitled "Underwriting—Lock-Up Agreements" below, we, each of our directors and officers and substantially all of the holders of at least one-half percent or more of our common stock on a fully diluted basis immediately prior to the consummation of this offering, have agreed, subject to specified exceptions, not to, directly or indirectly, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock or (ii) enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock, without the prior written consent of Maxim Group LLC, for a period of 180 days following the date of this prospectus for the offering.

Holders of our Series A convertible preferred stock, Series A-1 convertible preferred stock and Series B convertible preferred stock are parties to our Second Amended and Restated Investors' Rights Agreement, dated as of July 11, 2014. Pursuant to the terms of this agreement, each holder agreed that they will not engage in the type of transactions set forth above, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to our registration of shares of Common Stock or any other equity securities under the 1933 Act on a registration statement on Form S-1 in connection with an initial public offering, and ending on the date

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specified by us and the managing underwriter. Such termination date would not exceed 180 days, or such other period as we may request or an underwriter to accommodate regulatory restrictions on (1) the publication or other distribution of research reports, and (2) analyst recommendations and opinions, including but not limited to, the restrictions contained in FINRA Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto.

**Equity Incentive Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding stock options and common stock issuable under our equity incentive plans. We expect to file the registration statement covering such shares shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to the expiration of any applicable lock-up period and compliance with the resale provisions of Rule 144. For more information on our equity incentive plans, see "Executive Compensation—Stock Incentive Plans."

**Registration Rights**

Upon the closing of this offering, holders of a total of 5,143,229 shares of our common stock that will be outstanding after this offering, which includes shares of common stock issuable upon exercise of outstanding warrants, are entitled to demand that we file a registration statement or request that we cover their shares by a registration statement that we otherwise file. For more information, see "Description of Capital Stock—Registration Rights." Except for shares purchased by affiliates, registration of their shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement, subject to the expiration of the lock-up period and to the extent these shares have been released from any repurchase option that we may hold.

**MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS  
FOR NON-UNITED STATES HOLDERS OF COMMON STOCK**

The following is a general discussion of material United States federal income tax considerations relating to ownership and disposition of our common stock by a non-United States holder. For purposes of this discussion, the term "non-United States holder" means a beneficial owner of our common stock that is not, for United States federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated as a corporation for United States federal income tax purposes, created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is subject to United States federal income taxation regardless of its source; or
- a trust, if a United States court is able to exercise primary supervision over the administration of the trust and one or more United States persons have authority to control all substantial decisions of the trust or if the trust has a valid election to be treated as a United States person under applicable United States Treasury regulations.

This discussion is based on current provisions of the United States Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed United States Treasury regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-United States holders described in this prospectus. In addition, the Internal Revenue Service, or the IRS, could challenge one or more of the tax consequences described in this prospectus.

We assume in this discussion that each non-United States holder holds shares of our common stock as a capital asset (generally, property held for investment). This discussion does not address all aspects of United States federal income taxation that may be relevant to a particular non-United States holder in light of that non-United States holder's individual circumstances nor does it address any aspects of United States federal estate or gift taxes, and state, local or non-United States taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-United States holder and does not address the special tax rules applicable to particular non-United States holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain United States expatriates.

In addition, this discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other entities which are pass-through entities for United States federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other pass-through entity, as applicable.

**Prospective investors should consult their tax advisors regarding the United States federal, state, local and non-United States income and other tax considerations of acquiring, holding and disposing of our common stock.**

## **Dividends**

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we make distributions of cash or property on our common stock, those distributions generally will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-United States holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "Gain on Disposition of Common Stock."

Dividends paid to a non-United States holder generally will be subject to withholding of United States federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-United States holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-United States holder within the United States, are generally exempt from the 30% withholding tax if the non-United States holder satisfies applicable certification and disclosure requirements by providing a properly executed IRS Form W-8ECI (or successor form). However, such United States effectively connected income, net of specified deductions and credits, is taxed at the regular graduated United States federal income tax rates applicable to United States persons (as defined in the Code). Any United States effectively connected income received by a non-United States holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-United States holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN (or successor form) and satisfy applicable certification and other requirements. Non-United States holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-United States holder that is eligible for a reduced rate of United States withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

## **Gain on Disposition of Common Stock**

A non-United States holder generally will not be subject to United States federal income tax on gain realized on a disposition of our common stock unless:

- the gain is effectively connected with the non-United States holder's conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-United States holder in the United States; in these cases, the non-United States holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to United States persons, and, if the non-United States holder is a foreign corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the non-United States holder is a non-resident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the non-United States holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by United States-source capital losses of the non-United States holder, if any; or
- we are or have been, at any time during the five-year period preceding such disposition (or the non-United States holder's holding period, if shorter) a "United States real property holding corporation." Generally, a corporation is a "United States real property holding corporation" if the fair market value of its "United States real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "United States real property holding corporation" for United States federal income tax purposes. Even if we are or were to become a United States real property holding corporation, gains realized by a non-United States holder on a disposition of our common stock will not be subject to United States federal income tax if our common stock is regularly traded on an established securities market and the non-United States holder holds no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the non-United States holder's holding period. No assurance can be provided that our common stock will continue to be regularly traded on an established securities market for purposes of the rule described above.

## **Information Reporting and Backup Withholding**

We must report annually to the IRS and to each non-United States holder payments of dividends on our common stock to such holder and the tax withheld, if any, with respect to such dividends. Non-United States holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 28%, with respect to dividends on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a non-United States holder, or otherwise establishes an exemption. Dividends paid to non-United States holders subject to withholding of United States federal income tax, as described above under "—Dividends," generally will be exempt from United States backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-United States holder effected by or through the United States office of any broker, United States or foreign, unless the holder certifies its status as a non-United States holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information

reporting and backup withholding will not apply to a payment of disposition proceeds to a non-United States holder where the transaction is effected outside the United States through a non-United States office of a broker. However, for information reporting purposes, dispositions effected through a non-United States office of a broker with substantial United States ownership or operations generally will be treated in a manner similar to dispositions effected through a United States office of a broker. Non-United States holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-United States holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-United States holder can be refunded or credited against the non-United States holder's United States federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

#### **Recently-Enacted Legislation Relating to Foreign Accounts**

Legislation enacted in March 2010, commonly referred to as FATCA, generally will impose a 30% withholding tax on dividends of, and gross proceeds from the sale or disposition, of our common stock if paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) the non-financial foreign entity identifies its "substantial United States owner" (as defined in the Code) or certifies that it does not have any substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity is otherwise exempt under FATCA.

Pursuant to final regulations issued by the United States Department of Treasury and recently issued guidance, withholding under FATCA will only apply (i) to payments of dividends on our common stock made after June 30, 2014 and (ii) to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2016. Under certain circumstances, a non-United States holder may be eligible for refunds or credits of the tax. Non-United States holders should consult their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

**The preceding discussion of material United States federal tax considerations is for general information only. It is not tax advice. Prospective investors should consult their tax advisors regarding the particular United States federal, state, local and non-United States tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.**



## UNDERWRITING

As of the date of this prospectus, we have entered into an underwriting agreement with Maxim Group LLC, or Maxim, acting as sole book running manager and representative for the underwriters named below. Subject to the terms and conditions of the underwriting agreement, the underwriters named below have agreed to purchase, and we have agreed to sell to them, the number of shares of our common stock at the initial public offering price, less the underwriting discounts and commissions, as set forth on the cover page of this prospectus:

<u>Underwriter</u>	<u>Number of Shares</u>
Maxim Group LLC	—
Laidlaw & Company (UK) Ltd.	—
<b>Total</b>	<b>4,230,769</b>

All of the shares to be purchased by the underwriters will be purchased from us.

The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the shares of common stock offered by us in this prospectus are subject to various conditions, including the approval of certain legal matters by their counsel. The shares of common stock are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them. The underwriters reserve the right to withdraw, cancel or modify the offer and to reject orders in whole or in part.

The underwriting agreement provides that the underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken, other than those shares covered by the over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

### Over-Allotment Option

We have granted an option to the underwriters to purchase up to 15% of the total number of shares of common stock at the initial public offering price per share, less the underwriting discount, set forth on the cover page of this prospectus. This option is exercisable during the 45-day period after the date of this prospectus. The underwriters may exercise this option only to cover over-allotments made in connection with this offering. If the underwriters exercise this option in whole or in part, then the underwriters will be severally committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of our common stock in proportion to their respective commitments set forth in the prior table.

### Discounts and Commissions

The representative has advised us that the underwriters propose to offer the shares of common stock to the public at the initial public offering price per share set forth on the cover page of this prospectus. The underwriters may offer shares to securities dealers at that price less a concession of not more than \$            per share, of which up to \$            per share may be reallocated to other dealers. After the initial offering to the public, the public offering price and other selling terms may be changed by the representative.

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The following table summarizes the underwriting discounts and commissions and proceeds, before expenses, to us assuming both no exercise and full exercise by the underwriters of their over-allotment option:

	Per Share	Total	
		Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discounts and commissions(1)	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

- (1) The underwriting discounts and commissions do not include the Underwriters' Warrants or expense reimbursement as described below.

We estimate the expenses of this offering payable by us, not including underwriting discounts and commissions or the expense reimbursement described in the subsequent sentence, will be approximately \$2.2 million. We have agreed to pay the underwriters a non-accountable expense allowance in an amount of 1.5% of the gross proceeds of this offering, for certain of their expenses incurred in connection with this offering, such as background check fees, cost for book building, prospectus tracking and compliance software and road show expenses, but excluding any legal fees. In addition, we have agreed to reimburse the underwriters for its legal fees incurred in connection with this offering in an amount up to \$100,000.

### **Underwriters' Warrants**

Upon the closing of this offering, we have agreed to issue to the underwriters warrants to purchase a number of shares of our common stock equal to 1% of the total shares of our common stock sold in this initial public offering, excluding any shares that may be sold pursuant to the underwriter's exercise of the over-allotment option, or Underwriters' Warrants. The Underwriters' Warrants will be exercisable at a per share exercise price equal to 115% of the initial public offering price, and may be exercised on a cashless basis. The Underwriters' Warrants are exercisable commencing on the effective date of the registration statement related to this offering, and will be exercisable for five years. The Underwriters' Warrants are not redeemable by us. The Underwriters' Warrants, collectively, also provide for (i) one demand registration of the shares of common stock underlying the Underwriters' Warrants at our expense, (ii) one demand registration of shares of common stock underlying the Underwriters' Warrants at the warrant holders' expense, and (iii) unlimited "piggyback" registration rights with respect to the registration of the shares of common stock underlying the Underwriters' Warrants at our expense, during the five year period commencing upon the effective date of the registration statement related to this offering.

The Underwriters' Warrants and the shares of common stock underlying the Underwriters' Warrants have been deemed compensation by the Financial Industry Regulatory Authority, or FINRA, and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The underwriters, or permitted assignees under such rule, may not sell, transfer, assign, pledge, or hypothecate the Underwriters' Warrants or the securities underlying the Underwriters' Warrants, nor will the underwriters, or permitted assignees engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the Underwriters' Warrants or the underlying shares of common stock for a period of 180 days from the effective date of the registration statement, except that they may be transferred, in whole or in part, by operation of law or by reason of our reorganization, or to any underwriter and selected dealer participating in the offering and their officers or partners if the Underwriters' Warrants or the underlying shares of common stock so transferred remain subject to the foregoing lock-up restrictions for the remainder of the time period. The Underwriters' Warrants will provide for adjustment in the number and price of the Underwriters'

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Warrants and the shares of common stock underlying such Underwriters' Warrants in the event of recapitalization, merger, stock split or other structural transaction, or a future financing undertaken by us.

### **Lock Up Agreements**

We, each of our directors and officers and substantially all of the holders of at least one-half percent or more of our common stock on a fully diluted basis immediately prior to the consummation of this offering have agreed or are otherwise contractually restricted for a period of 180 days after the date of this prospectus, without the prior written consent of Maxim, not to directly or indirectly:

- issue (in the case of us), offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock;
- in the case of us, file or cause the filing of any registration statement under the Securities Act with respect to any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock, other than registration statements on Form S-8 filed with the SEC after the closing date of this offering; or
- enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock,

whether any transaction described in any of the foregoing bullet points is to be settled by delivery of our common stock or other capital stock, other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing.

There are no existing agreements between the underwriters and any person who will execute a lock-up agreement in connection with this offering providing consent to the sale of shares prior to the expiration of the lock-up period. The lock up does not apply to the issuance of shares upon the exercise of rights to acquire shares of common stock pursuant to any existing stock option or the conversion of any of our preferred convertible stock.

Holders of our Series A convertible preferred stock, Series A-1 convertible preferred stock and Series B convertible preferred stock are parties to our Second Amended and Restated Investors' Rights Agreement, dated as of July 11, 2014. Pursuant to the terms of this agreement, each holder agreed that they will not engage in the type of transactions set forth above, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to our registration of shares of Common Stock or any other equity securities under the 1933 Act on a registration statement on Form S-1 in connection with an initial public offering, and ending on the date specified by us and the managing underwriter. Such termination date would not exceed 180 days, or such other period as we may request or an underwriter to accommodate regulatory restrictions on (1) the publication or other distribution of research reports, and (2) analyst recommendations and opinions, including but not limited to, the restrictions contained in FINRA Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto.

### **Indemnification of Underwriters**

The underwriting agreement provides that we will indemnify the underwriters against certain liabilities that may be incurred in connection with this offering, including liabilities under the Securities

Act of 1933, or to contribute payments that the underwriters may be required to make in respect thereof.

## **Stabilization**

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more shares than they are obligated to purchase under the underwriting agreement, creating a short position in our common stock. 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 underwriter is not greater than the number of shares that it 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. To close out a short position or to stabilize the price of our common stock, the underwriters may bid for, and purchase, common stock in the open market. The underwriters may also elect to reduce any short position by exercising all or part of the over-allotment option. In determining the source of common stock 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 it 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.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing our common stock in this offering because the underwriter repurchases that stock in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, shares of our common stock in market making transactions, including "passive" market making transactions as described below.

The foregoing transaction may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on the NASDAQ Capital Market or otherwise.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in our common stock on the NASDAQ Capital Market immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act of 1934. Rule 103 generally provides that:

- a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers;
- net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume in our common stock during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and
- passive market making bids must be identified as such.

Passive market making may stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail and, if commenced, may be discontinued at any time.

### **Right of First Refusal**

Starting on the date of the commencement of sales of shares of our common stock pursuant to this offering and for a period of 15 months thereafter, we have granted Maxim a right of first refusal on any transaction where we have elected to employ an investment banker to act as lead managing underwriter and sole book runner, with at least 75% of the economics for any and all future public and private equity and debt offerings (excluding commercial bank debt), during such 15-month period, in which we, any successor to us or any of our subsidiaries engage. The 15-month right of first refusal period shall not be extended without our prior written consent, and if extended, shall not have a duration of more than three years from the date of the commencement of sales of shares of our common stock pursuant to this offering.

### **Discretionary Accounts**

The underwriters have informed us that they do not intend to confirm sales to accounts over which they exercise discretionary authority in excess of five percent of the total number of shares of common stock offered by them.

### **Pricing of this Offering**

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price for our common stock was determined between us and the representatives of the underwriters. The factors considered in determining the initial public offering price included:

- prevailing market conditions;
- our results of operations and financial condition;
- financial and operating information and market valuations with respect to other companies that we and the representatives of the underwriters believe to be comparable or similar to us;
- the present state of our development; and
- our future prospects.

An active trading market for our common stock may not develop. It is possible that the market price of our common stock after this offering will be less than the initial public offering price.

### **NASDAQ Capital Market Listing**

Our common stock was approved for listing on the NASDAQ Capital Market under the symbol "CERC."

**LEGAL MATTERS**

The validity of the shares of common stock offered hereby is being passed upon for us by Morgan, Lewis & Bockius LLP, Philadelphia, Pennsylvania. The underwriters are being represented by Loeb & Loeb LLP, New York, New York.

## **EXPERTS**

The financial statements of Cerecor Inc. at December 31, 2013 and 2014, and for each of the two years in the period ended December 31, 2014, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm 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 being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 400 E Pratt Street, Suite 606, Baltimore, Maryland 21202 or telephoning us at (410) 522-8707.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at [www.cerecor.com](http://www.cerecor.com), at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website incorporated by reference in, and is not part of, this prospectus.



**CERECOR, INC.**

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**Unaudited Financial Statements**

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Cerecor Inc.

We have audited the accompanying balance sheets of Cerecor Inc. as of December 31, 2013 and 2014, and the related statements of operations, convertible preferred stock and stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2014. 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 financial position of Cerecor Inc. at December 31, 2013 and 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

The accompanying 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 has recurring losses from operations, negative cash flows from operations and has a net capital deficiency that 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Baltimore, Maryland

April 29, 2015, except for the third and fourth paragraph of Note 14 as to which the date is September 4, 2015

**CERECOR INC.****Balance Sheets**

	<u>December 31,</u>	
	<u>2013</u>	<u>2014</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,421,480	\$ 11,742,349
Prepaid expenses and other current assets	714,280	360,307
Restricted cash—current portion	—	58,333
Total current assets	4,135,760	12,160,989
Restricted cash, net of current portion	175,000	117,165
Deferred financing costs	698,853	—
Property and equipment, net	65,987	38,740
Total assets	<u>\$ 5,075,600</u>	<u>\$ 12,316,894</u>
<b>Liabilities, convertible preferred stock and stockholders' deficit</b>		
Current liabilities:		
Current portion of long term debt, net of discount	\$ —	\$ 1,905,879
Accounts payable	1,639,505	931,139
Accrued expenses and other current liabilities	994,555	975,114
Warrant liability	431,582	69,684
Investor rights obligation	—	1,112,000
Total current liabilities	3,065,642	4,993,816
Long term debt, net of current portion and discount	—	5,308,211
Total liabilities	3,065,642	10,302,027
Convertible preferred stock:		
Series A—\$0.001 par value; 31,500,000 and 31,116,391 shares authorized at December 31, 2013 and 2014, respectively; 31,116,391 shares issued and outstanding at December 31, 2013 and 2014, respectively (aggregate liquidation preference of \$23,337,293 at December 31, 2014)	19,856,632	10,462,885
Series A-1—\$0.001 par value; 20,000,000 and 9,074,511 shares authorized at December 31, 2013 and 2014, respectively, 9,074,511 shares issued and outstanding at December 31, 2013 and 2014, respectively (aggregate liquidation preference of \$6,805,883 at December 31, 2014)	1	3,389,331

See accompanying notes to financial statements.

**CERECOR INC.****Balance Sheets (Continued)**

	<u>December 31,</u>	
	<u>2013</u>	<u>2014</u>
Series B—\$0.001 par value; 0 and 115,000,000 shares authorized at December 31, 2013 and 2014, respectively, 0 and 58,948,735 shares issued and outstanding at December 31, 2013 and 2014, respectively (aggregate liquidation preference of \$17,678,726 at December 31, 2014)	—	14,493,315
Total convertible preferred stock	19,856,633	28,345,531
Stockholders' deficit:		
Common Stock—\$0.001 par value, 167,000,000 and 230,000,000 shares authorized at December 31, 2013 and 2014, respectively, 642,844 and 649,721 shares issued and outstanding at December 31, 2013 and 2014, respectively	643	650
Additional paid-in capital	9,170,468	16,742,063
Accumulated deficit	(27,017,786)	(43,073,377)
Total stockholders' deficit	(17,846,675)	(26,330,664)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 5,075,600</u>	<u>\$ 12,316,894</u>

See accompanying notes to financial statements.

**CERECOR INC.****Statements of Operations**

	Years Ended December 31,	
	2013	2014
Operating expenses:		
Research and development	\$ 8,914,084	\$ 12,240,535
General and administrative	4,020,364	4,875,030
Total operating expenses	12,934,448	17,115,565
Loss from operations	(12,934,448)	(17,115,565)
Other income (expense):		
Change in fair value of warrant liabilities and Investor Rights Obligation	(121,115)	2,266,161
Interest income (expense), net	10,555	(1,206,187)
Total other income (expense)	(110,560)	1,059,974
Net loss	\$ (13,045,008)	\$ (16,055,591)
Net loss attributable to common stockholders	\$ (13,126,972)	\$ (3,521,153)
Net loss per share of Common Stock, basic and diluted	\$ (20.72)	\$ (5.48)
Weighted-average shares of Common Stock outstanding, basic and diluted	633,669	642,052
Pro forma net loss per share of Common Stock—basic and diluted (unaudited)		\$ (1.01)
Pro forma weighted-average shares of Common Stock outstanding, basic and diluted (unaudited)		3,501,768

See accompanying notes to financial statements.

CERECOR INC.

Statements of Convertible Preferred Stock and Stockholders' Deficit

For the Period from January 1, 2013 to December 31, 2014

	Series A, A-1 and B Convertible Preferred Stock		Stockholders' Deficit				
	Shares	Amount	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
			Shares	Amount			
<b>Balance, January 1, 2013</b>	<b>31,116,391</b>	<b>\$ 19,856,632</b>	<b>642,844</b>	<b>\$ 643</b>	<b>\$ 2,591,397</b>	<b>\$ (13,972,778)</b>	<b>\$ (11,380,738)</b>
Issuance of Series A-1 Convertible Preferred Stock	9,074,511	6,567,064	—	—	—	—	—
Discount for beneficial conversion feature on A-1 Convertible Preferred Stock	—	(6,567,064)	—	—	6,567,064	—	6,567,064
Offering costs paid for A-1 Convertible Preferred Stock issuance	—	—	—	—	(736,640)	—	(736,640)
Accretion of A-1 Convertible Preferred Stock beneficial conversion feature discount	—	1	—	—	(1)	—	(1)
Stock-based compensation	—	—	—	—	748,648	—	748,648
Net Loss	—	—	—	—	—	(13,045,008)	(13,045,008)
<b>Balance, December 31, 2013</b>	<b>40,190,902</b>	<b>19,856,633</b>	<b>642,844</b>	<b>643</b>	<b>9,170,468</b>	<b>(27,017,786)</b>	<b>(17,846,675)</b>
Extinguishment upon Modification of Series A and A-1 Convertible Preferred Stock and issuance of common stock dividends	—	(6,004,417)	6,877	7	6,004,604	—	6,004,611
Reclassification of common stock warrants from liabilities to equity	—	—	—	—	426,303	—	426,303
Conversion of Convertible Promissory Notes in Exchange for Series B Convertible Preferred Stock	5,597,618	1,405,003	—	—	—	—	—
Conversion of Demand Notes in Exchange for Series B Convertible Preferred Stock, net of Investors Rights Obligation	3,333,331	837,313	—	—	—	—	—
Issuance of Series B Convertible Preferred Stock net of issuance costs and Investors Rights Obligation	50,017,786	12,250,999	—	—	54,107	—	54,107
Stock-based compensation	—	—	—	—	1,086,581	—	1,086,581
Net Loss	—	—	—	—	—	(16,055,591)	(16,055,591)
<b>Balance, December 31, 2014</b>	<b>99,139,637</b>	<b>\$ 28,345,531</b>	<b>649,721</b>	<b>\$ 650</b>	<b>\$ 16,742,063</b>	<b>\$ (43,073,377)</b>	<b>\$ (26,330,664)</b>

See accompanying notes to financial statements.

**CERECOR INC.**

**Statements of Cash Flows**

	<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2014</b>
<b>Operating activities</b>		
Net loss	\$(13,045,008)	\$(16,055,591)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	20,032	28,943
Loss on disposition of assets	—	17,806
Stock-based compensation expense	748,648	1,086,581
Write off of deferred public offering costs	—	1,064,106
Non-cash interest expense	—	989,258
Non-cash expense related to issuance of warrants	25,811	—
Change in fair value of warrant liabilities and Investor Rights Obligation	121,115	(2,266,161)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(271,004)	353,973
Restricted cash	(175,000)	(498)
Accounts payable	818,391	(708,366)
Accrued expenses and other current liabilities	271,875	(28,400)
Net cash used in operating activities	<u>(11,485,140)</u>	<u>(15,518,349)</u>
<b>Investing activities</b>		
Purchase of property and equipment	(29,268)	(19,502)
Net cash used in investing activities	<u>(29,268)</u>	<u>(19,502)</u>
<b>Financing activities</b>		
Proceeds from issuance of convertible promissory notes and demand notes	—	2,249,666
Proceeds from issuance of term loan, net of costs	—	7,390,000
Proceeds from issuance of Series A-1 Convertible Preferred Stock, and Common Stock warrants, net of offering costs	6,115,080	—
Deferred financing costs	(698,853)	(365,253)
Proceeds from issuance of Series B Convertible Preferred Stock and Common Stock warrants, net of offering costs	—	14,584,307
Net cash provided by financing activities	<u>5,416,227</u>	<u>23,858,720</u>
Increase (decrease) in cash and cash equivalents	<u>(6,098,181)</u>	<u>8,320,869</u>
Cash and cash equivalents at beginning of period	9,519,661	3,421,480
Cash and cash equivalents at end of period	<u>\$ 3,421,480</u>	<u>\$ 11,742,349</u>
<b>Supplemental disclosures of cash flow information</b>		
Cash paid for interest	<u>\$ —</u>	<u>\$ 173,514</u>
<b>Supplemental disclosures of noncash financing activities:</b>		
Conversion of promissory and demand notes into Series B Convertible Preferred Stock	<u>\$ —</u>	<u>\$ 2,249,666</u>
Reclassification of Common Stock warrants from liabilities to equity	<u>\$ —</u>	<u>\$ 426,303</u>
Allocation of debt and equity proceeds to Investor Rights Obligation	<u>\$ —</u>	<u>\$ 2,598,510</u>
Extinguishment upon modification of Series A and A-1 Convertible Preferred Stock	<u>\$ —</u>	<u>\$ 12,534,438</u>

See accompanying notes to financial statements.

**CERECOR INC.**

**Notes to Financial Statements**

**As of and for the Years Ended December 31, 2014 and 2013**

**1. BUSINESS**

***Description of Business and Organization***

Cerecor Inc. (the "Company" or "Cerecor") was incorporated on January 31, 2011 in Delaware as Ceregen Corporation and subsequently changed the name to Cerecor Inc. in March 2011. The Company is a clinical-stage biopharmaceutical company with the goal of becoming a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. The Company's operations since inception have been limited to organizing and staffing the Company, acquiring rights to and developing certain product candidates and its product platform, business planning and raising capital.

***Liquidity***

The Company's financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should the Company be unable to continue to fund its operations. The Company has not generated any product revenues and has not yet achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and if achieved, could be sustained on a continuing basis.

The Company has incurred recurring operating losses since inception. For the year ended December 31, 2014, the Company incurred a net loss of \$16,055,591 and generated negative cash flows from operations of \$15,518,349. As of December 31, 2014, the Company had an accumulated deficit of \$43,073,377. The Company has not generated any product revenue to date. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to the clinical development of its product candidates, its product platform, its preclinical programs, business development and the development of its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy. To fully execute its business plan, the Company will need to complete certain research and development activities, have positive clinical trial results and obtain marketing approval for its product candidates, which may span many years, and may ultimately be unsuccessful. Any delays in completing these activities or negative clinical trial results could adversely impact the Company. The Company plans to meet its capital requirements primarily through a combination of equity and debt financings, collaborations, strategic alliances and marketing distribution or licensing arrangements and in the longer term, revenue from product sales to the extent its product candidates receive marketing approval and are commercialized. There can be no assurance, however, that the Company will be successful in obtaining financing at the level needed to sustain operations and develop its product candidates or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow. The Company currently anticipates that its cash and cash equivalents will be sufficient to meet its anticipated cash requirements through at least the end of the third quarter of 2015. These factors raise significant doubt about the Company's ability to continue as a going concern.



**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**2. SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

The accompanying financial statements have been prepared in conformity with U. S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

***Unaudited Pro Forma Presentation***

On December 17, 2013, the Company's board of directors authorized management of the Company to confidentially submit a registration statement to the Securities and Exchange Commission (the "SEC") for the Company to sell shares of its Common Stock (the "Common Stock") to the public. The unaudited pro forma net loss per share is computed using the weighted-average number of shares of Common Stock outstanding and gives effect to the automatic conversion of all outstanding shares of the Company's Preferred Stock into an aggregate of 3,980,422 shares of the Company's Common Stock as of January 1, 2014 or the date of original issuance, if later.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, other comprehensive income and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to clinical trial accruals, Investor Rights Obligation, and warrant liability. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

In addition, the Company utilizes estimates and assumptions in determining the fair value of its Common Stock. The Company granted stock options at exercise prices not less than the fair value of its Common Stock as determined by the board of directors, with input from management. Management uses the assistance of a third-party valuation firm in estimating the fair value of the Common Stock. The board of directors has determined the estimated fair value of the Common Stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the historic prices at which the Company sold shares of its Preferred Stock.

***Net Loss Per Share, Basic and Diluted***

Basic net loss per share of Common Stock is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of Common Stock outstanding during the period, excluding the dilutive effects of Preferred Stock, Investor Rights Obligation (see Note 10), warrants on Preferred Stock and Common Stock, stock options, Common Stock dividends on Series A-1 Convertible Preferred Stock and unvested restricted stock. Diluted net loss per share of Common Stock is computed by dividing the net loss attributable to common stockholders by the sum of the weighted-average number of shares of Common Stock outstanding during the period plus the potential dilutive effects of Preferred Stock, Investor Rights Obligation, warrants on Preferred Stock

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

and Common Stock, stock options, Common Stock dividends on Series A-1 Convertible Preferred Stock and unvested restricted stock outstanding during the period calculated in accordance with the treasury stock method, although these shares and options are excluded if their effect is anti-dilutive. In addition, the Company analyzes the potential dilutive effect of the outstanding Preferred Stock, Investor Rights Obligation, and warrants on Preferred Stock and Common Stock under the "if-converted" method when calculating diluted earnings per share, in which it is assumed that the outstanding security converts into Common Stock at the beginning of the period. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted net loss per share of Common Stock for the years ended December 31, 2013 and 2014.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The carrying amounts reported in the balance sheets for cash and cash equivalents are valued at cost, which approximates their fair value.

***Restricted Cash***

During the third quarter of 2013, the Company entered into a lease for new office space for its principal offices in Baltimore, Maryland. The Company has provided the landlord with a Letter of Credit in the amount of \$175,000 as security by the Company of the Company's obligations under the Lease. The Letter of Credit is supported by funds that are invested in a certificate of deposit. Provided there has been no event of default by the Company, the Company may request that the amount of the Letter of Credit be reduced by one-third (approximately \$58,000) at the end of each of the first three years of the lease term. At the expiration of the third year of the lease term, the Company shall deposit with Landlord the sum of \$13,000 as a security deposit.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains a portion of its cash and cash equivalent balances in the form of a money market account with a financial institution that management believes to be creditworthy. The Company has no financial instruments with off-balance sheet risk of loss.

***Deferred Offering Costs***

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs (non-current) until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the equity financing for which those costs relate no longer be considered probable of being consummated, all deferred offering costs will be charged to operating expenses in the statement of operations at such time. The Company incurred and deferred offering costs of \$698,853 during the year ended December 31, 2013. These costs were expensed in their entirety during 2014 upon the Company's determination that the equity financing was no longer probable of being consummated.

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Prior to this determination, the Company incurred and expensed an additional \$365,253 in offering costs during the year ended December 31, 2014.

***Debt Issuance Costs***

The Company may record debt and equity discounts in connection with raising funds through the issuance of convertible notes or equity instruments. These discounts may arise from (i) the receipt of proceeds less than the face value of the convertible notes or equity instruments, (ii) allocation of proceeds to beneficial conversion features and/or (iii) recording derivative liabilities related to embedded features. These costs are amortized over the life of the debt to interest expense utilizing the effective interest method. If a repayment, extinguishment or conversion of the underlying debt occurs, a proportionate share of the unamortized discount is immediately expensed.

***Property and Equipment***

Property and equipment consists of computers, office and laboratory equipment, and furniture and is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. The Company uses a life of four years for computers and software, and five years for equipment and furniture. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

***Impairment of Long-Lived Assets***

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset or asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset or asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use and eventual disposition of an asset or asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset or asset group over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

***Research and Development***

Research and development costs are expensed as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits and stock-based compensation of our research and development personnel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; other supplies; facilities, depreciation

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

and other expenses, which include direct and allocated expenses for rent, utilities and insurance; and costs associated with preclinical activities and regulatory operations.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors, such as clinical research organizations, with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

***Comprehensive Loss***

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss was equal to net loss for all periods presented.

***Income Taxes***

The Company accounts for income taxes under the asset and liability method in accordance with ASC 740, *Income Taxes* ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. The deferred tax asset primarily includes net operating loss and tax credit carryforwards, accrued expenses not currently deductible and the cumulative temporary differences related to certain research and patent costs, which have been charged to expense in the accompanying statements of operations but have been recorded as assets for income tax purposes. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. A full valuation allowance has been established against all of the deferred tax assets (see Note 12) as it is more likely than not that these assets will not be realized given the Company's history of operating losses. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position.

The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2014, the Company does not believe any material uncertain tax positions are present.

***Stock-Based Compensation***

At December 31, 2014, the Company had one stock-based compensation plan (see Note 11). The Company applies the provisions of ASC 718, *Compensation—Stock Compensation* ("ASC 718"), which

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including employee stock options in the statement of operations.

For stock options issued to employees and members of the board of directors for their services on the board of directors, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the Common Stock consistent with the expected life of the option, risk-free interest rates, the value of the Common Stock and expected dividend yields of the Common Stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock-based payments issued to non-employees are initially measured at their grant date fair values, are revalued as the underlying equity instruments vest and are recognized as expense over the earlier of the period ending with the performance commitment date or the date the services are completed in accordance with the provisions of ASC 718 and ASC 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50"). See Note 11 for a discussion of the assumptions used by the Company in determining the grant date fair value of options granted under the Black-Scholes option pricing model, as well as a summary of the stock option activity under the Company's stock-based compensation plan.

***Clinical Trial Expense Accruals***

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

years ended December 31, 2013 and December 31, 2014, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

***Segment Information***

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, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company and the chief executive officer view the Company's operations and manage its business as one operating segment. All long-lived assets of the Company reside in the United States.

***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue From Contracts With Customers*, ("ASU 2014-09"). Pursuant to ASU 2014-09, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. For a public entity, ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. The Company has not yet determined the impact of adoption on the financial statements.

On June 10, 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation ("Topic 915")*. The guidance is intended to reduce the overall cost and complexity associated with financial reporting for development stage entities without reducing the availability of relevant information. The FASB also believes the changes will simplify the consolidation accounting guidance by removing the differential accounting requirements for development stage entities. As a result of these changes, there no longer will be any accounting or reporting differences in GAAP between development stage entities and other operating entities. For organizations defined as public business entities, the presentation and disclosure requirements in Topic 915 will no longer be required starting with the first annual period beginning after December 15, 2014, including interim periods therein. Early application is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities). The Company early adopted this guidance during the year ended December 31, 2014 and, as a result, the Company no longer presents inception-to-date information in the statements of operations, cash flows, and stockholders' deficit.

In August 2014, FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard, but believes its adoption will have no impact on its financial position, results of operations or cash flows.

CERECOR INC.

Notes to Financial Statements (Continued)

As of and for the Years Ended December 31, 2014 and 2013

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

In November 2014, the FASB issued ASU No. 2014-16, *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share is more akin to Debt or to Equity*. The amendments in this update clarify how current GAAP should be interpreted in evaluating the economic characteristics and risks of a host contract in a hybrid financial instrument that is issued in the form of a share. Specifically, the amendments clarify that an entity should consider all relevant terms and features—including the embedded derivative feature being evaluated for bifurcation—in evaluating the nature of the host contract. The amendments in this update are effective for public companies for fiscal years and interim periods within those fiscal years, beginning after December 15, 2015 with early adoption permitted. The Company has adopted this guidance for the year ended December 31, 2014 and has properly applied it to its hybrid financial instruments.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. The guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The standard also aligns the GAAP presentation with International Financial Reporting Standards and will remedy the long-standing conflict with the guidance in FASB Concepts Statement No. 6, *Elements of Financial Statements*, which indicates that debt issuance costs do not meet the definition of an asset, because they provide no future economic benefit. For public companies, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. For all other entities, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within fiscal years beginning after December 15, 2016. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis. The Company is currently evaluating the potential impact of the adoption of this standard, but believes its adoption will have no impact on its financial position, results of operations or cash flows.

## CERECOR INC.

## Notes to Financial Statements (Continued)

As of and for the Years Ended December 31, 2014 and 2013

## 3. NET LOSS PER SHARE OF COMMON STOCK, BASIC AND DILUTED

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

	Year ended December 31, 2013	Year ended December 31, 2014
<b>Net loss per share, basic and diluted calculation:</b>		
Net loss	\$ (13,045,008)	\$ (16,055,591)
Extinguishment upon modification of Series A and A-1 Convertible Preferred Stock	—	\$ 12,534,438
Deemed dividend	(81,964)	—
Net loss attributable to Common Stockholders	<u>\$ (13,126,972)</u>	<u>\$ (3,521,153)</u>
Weighted-average common shares outstanding	<u>633,671</u>	<u>642,054</u>
Net loss per share, basic and diluted	<u>\$ (20.72)</u>	<u>\$ (5.48)</u>

The following outstanding securities at December, 31, 2013 and 2014 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	December 31, 2013	December 31, 2014
Series A Convertible Preferred Stock	31,116,391	31,116,391
Series A-1 Convertible Preferred Stock	9,074,511	9,074,511
Series B Convertible Preferred Stock	—	58,948,735
Common Stock dividends on Series A-1 Convertible Preferred Stock	2,846	—
Unvested restricted stock	7,142	—
Stock options	381,669	552,726
Warrants on Common Stock	512,686	681,858
Warrants on Preferred Stock	—	625,208
Investor Rights Obligation	—	53,351,117

## 4. FAIR VALUE MEASUREMENTS

ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.



**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**4. FAIR VALUE MEASUREMENTS (Continued)**

- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

At December 31, 2013 and 2014, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts payable, accrued expenses and other current liabilities, long term debt, the Series A-1 Convertible Preferred Stock warrant liability, the Investor Rights Obligation and the term loan warrant liability. The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, restricted cash, accounts payable, and accrued expenses and other current liabilities approximate their respective fair values because of the short-term nature of these accounts. The estimated fair value of the Company's debt of \$7.1 million as of December 31, 2014 was based on current interest rates for similar types of borrowings and is in Level Two of the fair value hierarchy.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities that are measured at fair value on a recurring basis:

	December 31, 2013		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets</b>			
Investments in money market funds*	\$ 3,272,811	\$ —	\$ —
<b>Liabilities</b>			
Series A-1 Convertible Preferred Stock Warrant Liability	\$ —	\$ —	\$ 431,582

	December 31, 2014		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets</b>			
Investments in money market funds*	\$ 11,251,724	\$ —	\$ —
<b>Liabilities</b>			
Investor Rights Obligation	\$ —	\$ —	\$ 1,112,000
Term Loan Warrant Liability	\$ —	\$ —	\$ 69,684

\* Investments in money market funds are reflected in cash and cash equivalents on the accompanying Balance Sheets.

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**4. FAIR VALUE MEASUREMENTS (Continued)**

***Level 3 Valuation***

The Series A-1 Convertible Preferred Stock warrant liability is recorded as warrant liability on the accompanying Balance Sheet at December 31, 2013. The Series A-1 Convertible Preferred Stock warrant liability was marked-to-market each reporting period with the change in fair value recorded to other income (expense) in the accompanying Statements of Operations until the warrants were exercised, expired or other facts and circumstances led the Series A-1 Convertible Preferred Stock warrant liability to be reclassified to stockholders' equity (which occurred in July 2014). The fair value of the Series A-1 Convertible Preferred Stock warrant liability was estimated using a Black-Scholes Option Pricing Model within a Monte Carlo simulation model framework. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants to purchase shares of Common Stock as of December 31, 2013, included (i) volatility ranging from 45.0% to 75.0%, (ii) risk free interest rate ranging from 0.07% to 1.38%, (iii) strike price (\$28.00), (iv) fair value of Common Stock (\$10.08), and (v) expected life ranging from 0.50 to 2.25 years. The warrants for Common Stock issued to holders of Series A-1 Convertible Preferred Stock contained provisions whereby the exercise price could be adjusted. Certain events were not deemed to be traditional dilution events under GAAP. Therefore the warrants were classified as a liability and subject to derivative accounting. The provision was amended in conjunction with the issuance of the Series B Convertible Preferred Stock in July 2014 and the warrants are no longer subject to such adjustments. The warrants were marked to market immediately before the amendment and then classified into permanent equity immediately thereafter.

The Common Stock warrants issued in connection with the convertible promissory notes (see Note 9) were classified as liabilities at the time of issuance due to the variable exercise price prior to completing a qualified financing event. The Common Stock warrant liability was marked-to-market each reporting period with the change in fair value recorded to other income (expense) in the accompanying Statements of Operations until the warrants were exercised, expired or other facts and circumstances led the Common Stock warrant liability to be reclassified to stockholders' equity (which occurred in July 2014 in connection with the issuance of the Series B Convertible Preferred Stock). The fair value of the Common Stock warrant liability was estimated using a Black-Scholes Option Pricing Model. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants to purchase shares of Common Stock as of July 2014 included (i) volatility of 70.0%, (ii) risk free interest rate ranging from 1.62% to 1.74%, (iii) strike price (\$5.32 - \$10.08) per share, (iv) fair value of Common Stock (ranging from (\$5.32 - \$10.08) per share, and (v) expected life ranging from 4.8 to 5.0 years. Upon completing the issuance of the Series B Convertible Preferred Stock in July 2014, the exercise price of the Common Stock warrants was fixed at \$8.40 per share. The warrants were marked to market immediately before the exercise price was fixed and then classified into permanent equity immediately thereafter.

The term loan warrant liability is recorded as warrant liability on the accompanying Balance Sheet at December 31, 2014. The term loan warrant liability is marked-to-market each reporting period with the change in fair value recorded to other expense in the accompanying Statements of Operations until the warrants are exercised, expire or other facts and circumstances lead the term loan warrant liability to be reclassified to stockholders' equity. The fair value of the term loan warrant liability is estimated using a Black-Scholes Option Pricing Model within a Monte Carlo simulation model framework. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****4. FAIR VALUE MEASUREMENTS (Continued)**

to purchase shares of Series B Convertible Preferred Stock as of December 31, 2014, include (i) volatility of 60.0%, (ii) risk free interest rate of 2.1%, (iii) strike price (\$0.2999), (iv) fair value of Series B Convertible Preferred Stock (\$0.18), and (v) expected life ranging from 8.23 years. Significant decreases in the Company's stock price volatility will significantly decrease the overall valuation of the Company's term loan warrant liability, while significant increases in the Company's stock price volatility will significantly increase the overall valuation.

The Investor Rights Obligation is recorded at fair value in its own line item on the Company's Balance Sheets and will expire at the earlier of (i) an IPO, (ii) a deemed liquidation event, or (iii) June 30, 2017. While outstanding, the Investor Rights Obligation is remeasured at each reporting period and changes in fair value are recorded as a component of other income or expense in the Company's Statement of Operations. The fair value of the Investor Rights Obligation was determined using a valuation model, which considers the probability of achieving certain milestones, the entity's cost of capital, the estimated period the rights will be outstanding, consideration received for the instrument with the rights, the number of shares to be issued to satisfy the rights, the price of such shares and any changes in the fair value of the underlying instrument. The significant assumptions used in preparing the option pricing model for valuing the Company's Investor Rights Obligation as of December 31, 2014, include (i) volatility (60.0%), (ii) risk free interest rate ranging from 0.05% to 0.63%, (iii) strike price (\$0.2999), (iv) fair value of Preferred Stock (ranging from \$0.00 to \$0.18), and (v) expected life ranging from 0.5 to 1.75 years. Significant decreases in the the price per share of the Company's Series B Convertible Preferred Stock and stock price volatility will significantly decrease the overall valuation of its Investor Rights Obligation, while significant increases will significantly increase the overall valuation.

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the Series A-1 Convertible Preferred Stock warrant liability for the year ended December 31, 2013:

	<u>Level 3</u> <u>Series A Convertible</u> <u>Preferred Stock Warrant</u> <u>Liability</u>
Balance at December 31, 2012	\$ —
Warrants issued in connection with Series A-1 Convertible Preferred Stock	310,467
Change in fair value of warrant liability	121,115
Balance at December 31, 2013	<u>\$ 431,582</u>

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****4. FAIR VALUE MEASUREMENTS (Continued)**

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the Series A-1 Convertible Preferred Stock, Convertible Promissory Notes and Term Loan warrant liabilities and the Investor Rights Obligation for the year ended December 31, 2014:

	<u>Warrant Liability</u>	<u>Investor Rights Obligation</u>	<u>Total</u>
Balance at December 31, 2013	\$ 431,582	\$ —	\$ 431,582
Issuance of warrants with debt and equity financings	844,056	—	844,056
Recording of Investor Rights Obligations at fair value	—	2,598,510	2,598,510
Change in fair value	(779,651)	(1,486,510)	(2,266,161)
Reclassification of liability to stockholders' equity	(426,303)	—	(426,303)
Balance at December 31, 2014	<u>\$ 69,684</u>	<u>\$ 1,112,000</u>	<u>\$ 1,181,684</u>

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2013 and 2014. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the years ended December 31, 2013 and 2014.

**5. DEFERRED FINANCING COSTS**

Deferred financing costs incurred in preparation for filing an IPO consisted of the following:

	<u>December 31,</u>	
	<u>2013</u>	<u>2014</u>
Legal fees	\$ 348,995	\$ 525,414
Accounting fees	284,858	435,410
Printing costs	65,000	103,282
Expense upon determination that consummation of offering is not probable	—	(1,064,106)
Total deferred financing costs	<u>\$ 698,853</u>	<u>\$ —</u>

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****6. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

	December 31,	
	2013	2014
Furniture and equipment	\$ 81,155	\$ 34,918
Computers and software	21,647	41,150
Total property and equipment	102,802	76,068
Less accumulated depreciation	(36,815)	(37,328)
Property and equipment, net	<u>\$ 65,987</u>	<u>\$ 38,740</u>

Depreciation expense was \$20,032 and \$28,943 for the years ended December 31, 2013 and December 31, 2014, respectively.

**7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES**

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2013	2014
Compensation and benefits	\$ 158,276	\$ 129,450
Research and development expenses	124,525	598,883
General and administrative	711,754	159,045
Accrued interest	—	87,736
Total accrued expenses and other current liabilities	<u>\$ 994,555</u>	<u>\$ 975,114</u>

**8. ASSET ACQUISITION AND LICENSE AGREEMENTS**

In May 2011, the Company entered into an asset purchase agreement (the "Fells Agreement") with Fells Laboratories LLC ("Fells") for the acquisition of certain assets owned or licensed by Fells, all related to a compound known as FP01. The Company also assumed certain contractual obligations relating to FP01. The principal assets acquired consisted of three patents owned by Fells and a license with Johns Hopkins University ("JHU"), which includes rights to two additional patents. According to the terms of the Fells Agreement, the Company paid \$540,000, which consisted of a \$340,000 upfront payment in May 2011, which was expensed as research and development during the period from January 31, 2011 to December 31, 2011 and a \$200,000 milestone payment in July 2012, which was expensed as research and development during the year ended December 31, 2012, upon the successful completion of the prototype of the formulation of FP01. The Company could have been required to pay up to an additional \$2.9 million to Fells upon the achievement of certain contingent development and regulatory milestones; however, Fells has disclaimed any right to receive any future payment under the Fells Agreement and, in addition, the Company has discontinued any further development of FP01 and has provided notice to JHU that the Company is terminating the JHU license effective June 15, 2015.

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****8. ASSET ACQUISITION AND LICENSE AGREEMENTS (Continued)**

The Company accounted for this transaction as an asset acquisition because it only acquired the assigned rights and technology and did not acquire any processes or activities. The majority shareholder of Fells is the Company's President and Chief Executive Officer.

Pursuant to the terms of the license agreement between JHU and Fells, which the Company assumed in the acquisition, the Company may be required to make contingent milestone payments to JHU of up to \$375,000 upon the achievement of certain development and regulatory milestones. The Company expensed \$27,500 and \$0 for the years ended December 31, 2013 and 2014, respectively, which has been recorded as research and development expenses in the accompanying Statements of Operations. The Company is not currently developing FP01 and does not expect to expense any additional fees to JHU unless the Company out-licenses FP01 to a third party for development.

In March 2013, the Company entered into an exclusive license agreement with Merck pursuant to which Merck granted the Company rights relating to certain small molecule compounds. In consideration of the license, the Company may be required to make initial payments totaling \$1,500,000. Pursuant to the license agreement the Company paid \$750,000 and upon achievement of FDA acceptance of Merck pre-clinical data and FDA approval of a Phase 3 clinical trial the Company will pay an additional \$750,000. The initial payment of \$750,000 was recorded as research and development expense in the accompanying Statement of Operations for the year ended December 31, 2013. Additional payments may be due upon achievement of development and regulatory milestones, including first commercial sale. Upon commercialization of an NR2B product, the Company is obligated to pay Merck milestones and royalties on net sales.

In March 2013, the Company entered into a separate exclusive license agreement with Merck pursuant to which Merck granted to the Company certain rights in small molecule compounds which are known to inhibit the activity of catechol-*O*-methyltransferase, or COMT. The Company made a \$200,000 upfront payment to Merck, which was recorded as research and development expense in the accompanying Statement of Operations for the year ended December 31, 2013. Under the agreement the Company is required to pay milestone payments upon achievement of various development and regulatory milestones. Upon commercialization of a COMT product, the Company is obligated to pay Merck a royalty on net sales of a COMT product.

**9. DEBT**

Debt consisted of the following:

	<u>December 31,</u> <u>2014</u>
Term loan	\$ 7,500,000
Less: debt discount	(285,910)
Term Loan, net of debt discount	7,214,090
Less: current portion, net of debt discount	(1,905,879)
Long term debt, net of current portion and debt discount	<u>\$ 5,308,211</u>

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****9. DEBT (Continued)*****Term Loan***

In August 2014, the Company received a \$7,500,000 secured term loan from a finance company. The loan is secured by a lien on all of the Company's assets, excluding intellectual property, which was subject to a negative pledge. The loan contains certain additional nonfinancial covenants. In connection with the loan agreement, the Company's cash and investment accounts are subject to account control agreements with the finance company that give the finance company the right to assume control of the accounts in the event of a loan default. Loan defaults are defined in the loan agreement and include, among others, the finance company's determination that there is a material adverse change in the Company's operations. Interest on the loan is at a rate of the greater of 7.95%, or 7.95% plus the prime rate as reported in The Wall Street Journal minus 3.25%. The current interest rate is 7.95%. The loan is interest-only for nine months, and is repayable in equal monthly payments of principal and interest of \$304,278 over 27 months. Cash interest expense of \$223,594 was recognized during the year ended December 31, 2014 in the accompanying Statement of Operations. Future principal payments are as follows:

<u>Year ending December 31,</u>	
2015	\$ 2,077,081
2016	3,335,122
2017	<u>2,087,797</u>
	<u>\$ 7,500,000</u>

Additionally, the lender was granted the right to participate in the first tranche of the Company's Series B Convertible Preferred Stock financing in an amount of up to \$1,000,000 to be funded on the date the loan agreement was entered into, and (b) in the second tranche of the Company's Series B Convertible Preferred Stock financing in an amount of up to \$1,000,000, on the same terms, conditions and pricing afforded to others participating in the applicable financing, if such second tranche occurs. The Lender exercised this right and in August 2014 invested \$1,000,000 in the Series B Convertible Preferred Stock financing (see Note 1). The right to participate in the second tranche will expire upon the closing of an IPO.

The Company accounted for the issuance of the term loan and Series B Convertible Preferred Stock financing as a bundled transaction to which a portion of the fair value of the Investor Rights Obligation was allocated to the term loan and Series B Convertible Preferred Stock equity offering based on relative fair value (see Note 10). Using the probability weighted expected return method, or PWERM, the Investor Rights Obligation was initially valued at \$162,407 of which the Company allocated \$143,252 as a debt discount against the carrying value of the term loan at the time of issuance.

The PWERM involves a forward-looking analysis of the possible future outcomes of a company. Discrete future outcomes considered under the PWERM included non-IPO market based outcomes as well as IPO scenarios. In the non-IPO scenarios, a large portion of the Company's equity value is allocated to the Preferred Stock to incorporate higher aggregate liquidation preferences. In the IPO scenarios, the equity value is allocated pro rata among the shares of Common Stock and each series of Preferred Stock, which causes the Common Stock to have a higher relative value per share than under the non-IPO scenario. The fair value of the Investor Rights Obligation determined using the IPO and

## CERECOR INC.

## Notes to Financial Statements (Continued)

As of and for the Years Ended December 31, 2014 and 2013

## 9. DEBT (Continued)

non-IPO scenarios are weighted according to the board of directors' estimate of the probability of each scenario.

In connection with the loan from the finance company, the Company issued a warrant to purchase 625,208 shares of Series B Convertible Preferred Stock at an exercise price of \$0.2999 per share that is exercisable for a period ending upon the earlier of ten years from the date of issuance and five years following an IPO. The Company's warrant to purchase shares of Series B Convertible Preferred Stock represented a freestanding financial instrument that was indexed to an obligation of the Company to repurchase its Series B Convertible Preferred Stock by transferring assets and therefore met the criteria to be classified as a liability under ASC 480, *Distinguishing Liabilities from Equity*. The Company records the warrant liability at its fair value using the Black-Scholes option pricing model and revalues the warrant at each reporting date. The following table summarizes the fair value and the assumptions used for the Black-Scholes option-pricing model for this warrant:

	Date of Issuance,	
	August 19, 2014	December 31, 2014
Fair value	\$ 115,056	\$ 69,684
Fair value of Series B Convertible Preferred Stock	\$ 0.25	\$ 0.20
Expected dividend yield	0.0%	0.00%
Risk-free interest rate	2.4%	2.1%
Expected stock price volatility	70.0%	60.0%
Expected term	9.8 years	8.3 years

Upon issuance of the term loan, the Company paid lender fees of \$110,000 and is required to pay a one-time fee at maturity of \$187,500. A portion of the Investor Rights Obligation was allocated to the term loan and equal to \$143,252 (as discussed above and see Notes 4 and 10). The lender fees, warrants, and Investor Rights Obligation were recorded as a discount to the carrying amounts of the current and long term portions of the term loan. Amortization of the debt discount and accretion of the one-time fee was \$68,861 and \$36,394, respectively, during the year ended December 31, 2014 and is reflected as a component of interest expense within the Company's Statements of Operations.

**Convertible Promissory Notes**

From April through June 2014, the Company entered into several convertible promissory notes for aggregate proceeds of \$1.25 million. The loans bear interest at an annual rate of 6.0% and mature within 12 months from their issuance date. In the event that the Company completed a qualified equity offering that generated aggregate proceeds of at least \$10 million, the notes would automatically convert into the shares issued in connection with the qualified equity offering and at a conversion price equal to 75% of the qualified equity offering price. The Company accounted for the notes as stock-settled debt, since the value of any future stock issued upon conversion will be equal to 125% of the principal and interest to which the Company amortized \$145,987 into earnings and recorded as interest expense over the term of the notes. In the event that an equity offering did not occur by the maturity date, all interest and principal would have become due. The notes converted on July 11, 2014 when the Series B Convertible Preferred Stock equity offering was completed. The principal amount of the notes, and interest of \$9,016, was converted at 75% of the Series B Convertible Preferred Stock original issuance price, or \$0.22492 per share, and the Company issued 5,597,618 shares of Series B Convertible Preferred Stock.



**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****9. DEBT (Continued)**

In connection with issuing the notes, the holders received warrants to purchase 148,854 shares of the Company's Common Stock. The warrants are exercisable at the option of the holder at any time during their five-year term at a price per share at which equity securities are sold in a qualified financing event or offered to the public in the event of an IPO. Upon completing the Series B Convertible Preferred Stock equity offering on July 11, 2014, a qualified financing event occurred and the holders are eligible to exercise their warrants, at any time, at an exercise price of \$8.40 per share. In the event of an IPO, change in control or capital restructuring, as set forth in the warrant, the Company will provide the holders of the warrants notification of such events to afford the holders the ability to exercise their warrants prior to the event. If the holder does not exercise the warrant, then the warrants shall expire in accordance with their terms. The exercise price of the warrants does not contain "down round" protection provisions.

Due to the variable exercise price and number of shares underlying the warrant prior to the completion of the qualified financing, the warrants were classified as liabilities and subject to derivative accounting. On July 11, 2014, the exercise price and number of shares underlying the warrant were fixed and the warrants were reclassified to permanent equity. At the time of the reclassification, the warrants had a fair value of \$379,000.

The Company recorded the warrant liability at its fair value using the Black-Scholes option pricing model and revalued the warrant at each reporting date. The following table summarizes the fair value and the assumptions used for the Black-Scholes option-pricing model for this warrant:

	<u>Dates of Issuance</u>	<u>July 11, 2014 Reclassification</u>
Fair value	\$729,000	\$379,000
Fair value of Common Stock	\$5.32 - \$10.08	\$5.32
Expected dividend yield	0.0%	0.0%
Risk-free interest rate	1.62% - 1.74%	1.65%
Expected stock price volatility	70.0%	70.0%
Expected term	4.8 - 5.0 years	4.8 - 4.9 years

The fair value of the warrants were \$729,000 at issuance and recorded as a discount to the face value of the convertible promissory notes and was fully amortized into interest expense prior to the conversion into shares of Series B Convertible Preferred Stock.

***Demand Notes***

On July 3, 2014, the Company issued \$999,666 in demand notes that were converted on July 11, 2014 upon completing the Series B Convertible Preferred Stock equity offering. The demand note holders were the majority participants in the Series B Convertible Preferred Stock equity offering. The purpose of the notes were to provide short term financing between the targeted closing date of Series B Convertible Preferred Stock equity offering, July 3, 2014, and the actual closing date of July 11, 2014. The demand notes converted at the original issuance price of Series B Convertible Preferred Stock of \$0.2999 per share, and the holders received 3,333,331 shares of Series B Convertible Preferred Stock (see Note 10). Interest at 0.31% was not paid due to the short term that the notes were outstanding.

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**

At December 31, 2014, the Company was authorized to issue two classes of stock, Common Stock and Preferred Stock. The total number of shares of capital stock the Company was authorized to issue was 385,190,902 of which 230,000,000 was Common Stock and 155,190,902 was Preferred Stock. All shares of Common and Preferred Stock have a par value of \$0.001 per share. 31,116,391 of the authorized shares of Preferred Stock are designated as Series A Convertible Preferred Stock and 9,074,511 of the authorized shares of Preferred Stock are designated as Series A-1 Convertible Preferred Stock and the remaining 115,000,000 shares have been designated as Series B Convertible Preferred Stock. The rights, preferences, privileges and restrictions granted to and imposed on Preferred Stock are described below.

***Preferred Stock Voting Agreement and Rights***

The holders of the Preferred Stock have the right to one vote for each share of Common Stock into which such share of Preferred Stock could then be converted. In addition, the holders of the shares of Series A Convertible Preferred Stock and Series A-1 Convertible Preferred Stock, exclusively and as a single class, shall be entitled to elect one director of the Company, the holders of the Shares of Series B Convertible Preferred Stock, exclusively and as a single class, shall be entitled to elect five directors of the Company and the holders of the shares of Common Stock, exclusively and as a separate class, shall be entitled to elect two directors of the Company. The holders of all classes of voting stock (including Preferred Stock) voting as a single class shall elect the balance of directors of the Company. In addition, upon a deemed liquidation event or a sale of the Company, in each case approved by the holders of a majority of the then outstanding shares of Preferred Stock and the board of directors, each stockholder of the Company has agreed to approve such deemed liquidation event or a sale of the Company and sell any shares held by such shareholder in connection with any such transaction.

***Preferred Stock Conversion***

Each share of Series A Convertible Preferred Stock will be convertible into 0.04464 shares of Common Stock, each share of Series A-1 Convertible Preferred Stock will be convertible into 0.05357 shares of Common Stock and each share of Series B Convertible Preferred Stock will be convertible into 0.03571 share of Common Stock, subject to certain anti-dilution protections, at the option of the holder. Each share of Preferred Stock will automatically convert upon (i) the closing of the sale of shares of Common Stock in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act, resulting in at least \$45.0 million of gross proceeds to the Company (a "qualified initial public offering"), or (ii) the occurrence of an event, specified by a vote or written consent of the holders of a majority of the then outstanding shares of Preferred Stock. As of December 31, 2014, the Preferred Stock is convertible into 3,980,422 shares of Common Stock.

***Preferred Stock Dividends***

Prior to the issuance of Series B Convertible Preferred Stock, the Series A Convertible Preferred Stock did not bear dividends. The Series A-1 Convertible Preferred Stock accrued dividends payable solely in shares of Common Stock at a rate of 2.5% per annum and could potentially increase up to 12.5% per annum if the Company did not complete a qualified IPO by certain dates. Accruing Common Stock dividends were only payable upon the conversion of Series A-1 Convertible Preferred

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)**

Stock into Common Stock or certain deemed liquidation events. Dividends on the Series A-1 Convertible Preferred Stock were considered a conversion rate adjustment, and therefore no dividends had been accrued as of December 31, 2013. Coinciding with the issuance of Series B Convertible Preferred Stock, the stock dividends earned through the July 11, 2014, or 6,877 shares of Common Stock, were issued as to the holders of Series A-1 Convertible Preferred Stock and thereafter those rights were terminated.

Since the issuance of Series B Convertible Preferred Stock, all series of Preferred Stock are entitled to a non-cumulative annual dividend of 8.0%. Dividends are paid when, as, and if declared by the board of directors.

***Preferred Stock Redemption Rights***

The Preferred Stock is subject to redemption under certain "deemed liquidation" events, as defined, and as such, the Preferred Stock is considered contingently redeemable for accounting purposes. Accordingly, the Preferred Stock has been recorded within temporary equity in the financial statements. The Company has not adjusted the Preferred Stock to its redemption amount at each reporting period, as the redemption of such Preferred Stock is not deemed probable of occurrence during the periods presented. The redemption of the Preferred Stock is not considered probable as the redemption is contingent on the occurrence of such "deemed liquidation" events, which include (i) the acquisition of the Company by another entity by means of any transaction or a series of related transactions, unless the existing stockholders of the Company continue to hold at least 50% of the voting power of the surviving or acquiring entity after such transaction; and (ii) a sale of all or substantially all of the assets of the Company. The Company has concluded that none of these events are probable during the periods presented.

***Preferred Stock Liquidation Preference***

In the event of any liquidation, dissolution or winding up of the Company prior to the conversion, the holders of the Preferred Stock will be entitled to a liquidation preference in pari passu before any liquidation preference payments are made to the Common shareholders. The liquidation preference payment is equal to the greater of (i) original issuance plus any declared but unpaid dividends, or (ii) the amount that a Preferred holder would have been entitled to receive if they had converted to common immediately prior to liquidation.

***Right of First Refusal and Co-sale Agreement***

The Preferred Stock holders along with the holders of Common Stock have entered into a Right of First Refusal and Co-Sale Agreement with the Company in order to provide certain restrictions on the transfer of capital stock and to grant first refusal and co-sale rights to the Company and to the holders of Preferred Stock.

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)**

***Investors' Rights Agreement and Registration Rights***

The holders of the Preferred Stock have certain registration rights with respect to the Common Stock into which the shares are convertible. If at any time after the earlier of three years after the date of the Investors' Rights Agreement or 180 days after the effective date of a registration statement for an IPO, the Company receives a request from the holders of a majority of the Series B Convertible Preferred Stock then outstanding that are registerable, the Company shall file a Form S-1 registration statement covering those shares with an anticipated offering price, net of expenses, of at least \$10 million. If at any time after the Company is eligible to use a Form S-3 registration statement, the Company receives a request from the holders of outstanding securities that are registerable, the Company shall file a registration statement on Form S-3 covering those shares so long as certain conditions are met, including an anticipated offering price, net of expenses, of at least \$1 million.

***Series A Convertible Preferred Stock Transactions***

On February 14, 2012, March 23, 2012 and April 4, 2012, the Company completed closings of its private placement offering of Series A Convertible Preferred Stock in the total amount of approximately \$19.0 million. The offering price for each unit was \$0.75, which consisted of one share of Series A Convertible Preferred Stock and a warrant. Each investor in the offering received a five-year warrant to purchase such number of the Company's shares of Common Stock equal to 25% of the number of shares of Series A Convertible Preferred Stock purchased by such investor at an exercise price equal to \$28.00 per share. The placement agent received an 8% placement fee and a 2% corporate finance fee totaling approximately \$1.9 million. The number of shares of Series A Convertible Preferred Stock issued in the three closings was 25,305,583 along with investor warrants to purchase 225,869 shares of Common Stock at an exercise price equal to \$28.00 per share. The placement agent received warrants to purchase 126,091 shares of Common Stock on the same terms and conditions as the other warrants that the purchasers of Series A Convertible Preferred Stock received in this offering.

On May 18, 2012, the Company completed a direct private placement of its Series A Convertible Preferred Stock in the amount of \$1.2 million also at a purchase price of \$0.75 per unit. The number of shares of Series A Convertible Preferred Stock issued in the closing was 1,600,000 along with warrants to purchase 14,284 shares of Common Stock at \$28.00 per share. On March 23, 2012, a convertible demand promissory note with an outstanding principal balance of \$3.0 million, plus accrued interest of \$58,000, was converted into 4,077,475 shares of Series A Convertible Preferred Stock along with warrants to purchase 36,406 shares of Common Stock at an exercise price equal to \$28.00 per share. Further, the Company paid \$375,000 to the placement agent as compensation for the direct private placement and conversion of the convertible demand promissory note and recorded the compensation as a reduction of the proceeds from the Series A Convertible Preferred Stock and warrants. In March 2012, an amount of \$100,000 due to a related party was converted into 133,333 shares of Series A Convertible Preferred Stock and a warrant to purchase 1,190 shares of Common Stock (see Note 8).

The net proceeds to the Company from these Series A Convertible Preferred Stock issuances after offering costs was approximately \$17.7 million.

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)**

In connection with the issuance of the Series B Convertible Preferred Stock in 2014, the holders of Series A Convertible Preferred Stock waived their contractual anti-dilution rights set forth in the Company's amended and restated articles of incorporation (as amended from time to time, "Articles"). In exchange for waiving this right, Company adjusted the conversion price for Series A Convertible Preferred Stock of \$0.75 per share to \$0.60 per share. With the assistance of a third party valuation firm, management determined the fair value of the Series A Convertible Preferred Stock to be \$0.34 per share at the time of extinguishment. The \$9,393,746 gain on extinguishment was equal to the excess carrying value of the Series A Convertible Preferred Stock of \$19,856,632 over the fair value of the amended Series A Convertible Preferred Stock of \$10,462,886. Because the underlying transaction was between the Company and its equity investors, the Company accounted for the extinguishment as a noncash gain to additional paid in capital in accordance with ASC 470-50-40-2 and included as a component of net loss attributable to common stockholders.

***Series A-1 Convertible Preferred Stock Transaction***

In August 2013, the Company completed a \$6.8 million private equity offering. The offering price for each unit was \$0.75, which consisted of one share of Series A-1 Convertible Preferred Stock and a warrant. The number of shares of Series A-1 Convertible Preferred Stock issued was 9,074,511 shares along with investor warrants to purchase 80,966 shares of Common Stock with an initial exercise price equal to (i) \$28.00 per share of Common Stock if such warrant is exercised prior to a qualified IPO or (ii) the public offering price for a share of Common Stock sold in a qualified IPO if such warrant is exercised after such qualified IPO, in each instance, subject to further adjustments as set forth in such warrants. The warrants expire on the fifth anniversary from their original issuance date. The net proceeds to the Company after offering costs were approximately \$6.1 million.

The gross proceeds of the offering were first allocated to the warrants based on the fair value of the warrants at that time, with the residual proceeds allocated to the Series A-1 Convertible Preferred Stock (\$6.6 million). All offering costs were allocated between the Series A-1 Convertible Preferred Stock (\$700,000—which reduced the initial carrying value of the Series A-1 Convertible Preferred Stock) and the warrants (\$27,000—which was recorded as general and administrative expenses in the 2013 statement of operations). In addition, the placement agent received, as compensation for the transaction, warrants to purchase 24,306 shares of Common Stock priced at \$21.00 per share. The fair value of the placement agent warrants was \$72,000 at the time of issuance, and that value was allocated to the Series A-1 Convertible Preferred Stock (\$69,000—which reduced the initial carrying value of the Series A-1 Convertible Preferred Stock) and the warrants (\$3,000—which was recorded as general and administrative expenses in the 2013 statement of operations). The fair value of all warrants associated with this transaction on the date of issuance was \$310,467 and was recorded as a long-term liability due to the fact that these warrants met the definition of derivative instruments and were not indexed to the Company's own stock. These warrants are required to be marked to fair value at each reporting period. Upon the issuance of Series B Convertible Preferred Stock, the exercise price of the A-1 warrants is no longer subject to adjustment. The A-1 warrants were marked to fair value immediately before the amendment and then classified into permanent equity immediately thereafter.

In connection with the issuance of the Series A-1 Convertible Preferred Stock, the Company recognized the intrinsic value of a beneficial conversion of \$6.6 million as additional paid-in capital.

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)**

The beneficial conversion amount was computed as the difference between the conversion price and the fair value of the Common Stock into which the Series A-1 Convertible Preferred Stock is convertible, multiplied by that number of shares issuable upon conversion. The beneficial conversion amount is equal to the entirety of the proceeds allocated to the Series A-1 Convertible Preferred Stock because the most beneficial conversion price is mathematically limitless by virtue of certain conversion adjustments associated with cumulative dividends. Specifically, the Series A-1 Convertible Preferred Stock conversion price is adjusted each period by annual cumulative dividends of 2.5% to be paid through the issuance of Common Stock only upon conversion. The effect of dividend adjustments to the conversion price could have ultimately resulted in a conversion price of less than \$0.001, unless the Series A-1 Convertible Preferred Stock was converted or redeemed earlier. The discount for the beneficial conversion feature was being accreted over the period in which the holders would realize the beneficial conversion feature, or 31 years. Upon the issuance of Series B Convertible Preferred Stock, the 2.5% dividend provision was amended which resulted in the reversal of the unamortized beneficial conversion feature discount of \$6.6 million. The Company concluded that a portion of the reacquisition price should be allocated to the repurchase of the beneficial conversion option. The amount of the reacquisition price allocated to the reacquisition of the beneficial conversion option was equal to the intrinsic value that was previously recognized for the beneficial conversion feature. The residual amount was allocated to the extinguishment of the Series A-1 Convertible Preferred Stock, and the difference between the residual amount allocated to the Series A-1 Convertible Preferred Stock and the carrying amount of the Series A-1 Convertible Preferred Stock was added to earnings available to common stockholders for purposes of computing earnings per share.

In addition, for any investor of Series A Convertible Preferred Stock who also participated in the Series A-1 Convertible Preferred Stock offering, the Company amended the terms of the original warrants issued with respect to such Series A Convertible Preferred Stock in 2012 reducing the exercise price from \$28.00 per share of Common Stock to \$14.00 per share of Common Stock provided that such investor purchased a minimum of 40% of their original Series A Convertible Preferred Stock investment.

In connection with the issuance of the Series B Convertible Preferred Stock in 2014, the holders of A-1 Preferred Stock waived their contractual anti-dilution rights under the Articles. In exchange for waiving this right, Company adjusted the conversion price for Series A-1 Convertible Preferred Stock of \$0.75 per share to \$0.50 per share and in exchange for waiving the 2.5% cumulative dividend right, the Company issued to the holders, 6,877 shares of Common Stock.

With the assistance of a third party valuation firm, management determined the fair value of the Series A-1 Convertible Preferred Stock to be \$0.37 per share at the time of extinguishment. The \$3,140,692 gain on extinguishment was equal to the excess carrying value of the Series A-1 Convertible Preferred Stock of \$1 plus the unamortized beneficial conversion feature of \$6,567,063, over the fair value of the amended Series A-1 Convertible Preferred Stock of \$3,389,330 and the fair value of the 6,877 shares of Common Stock of \$37,041. Because the underlying transaction was between the Company and its equity investors, the Company accounted for the extinguishment as a noncash charge to additional paid in capital in accordance with ASC 470-50-40-2.

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)**

***Series B Convertible Preferred Stock Transaction***

On July 11, 2014, the Company completed an initial closing of an equity offering for shares of its Series B Convertible Preferred Stock and on August 19, 2014 completed a second closing. Pursuant to the terms of the agreement, the Company issued an aggregate of 50,017,786 shares of Series B Convertible Preferred Stock at an original issuance price of \$0.2999 per share for gross proceeds of \$15,000,000.

In addition, and pursuant to the terms of, several convertible promissory notes issued from April through June 2014, the Company issued 5,597,618 shares of Series B Convertible Preferred Stock upon the conversion of the outstanding principal and interest due under the convertible promissory notes in the aggregate amount of \$1,259,016. The conversion price for the convertible promissory notes was equal to \$0.22492, or 75% of the original issuance price of the Series B Convertible Preferred Stock. The demand notes issued in July 2014, with an aggregate principal balance of \$996,666, was converted into 3,333,331 shares of Series B Convertible Preferred Stock at a conversion price of \$0.2999 per share. See Note 9 for additional information regarding the terms and provisions of the convertible promissory notes and demand notes.

The second closing of the Series B Convertible Preferred Stock equity offering was with the term loan lender. Pursuant to the same terms and conditions of the initial offering, the Company issued 3,334,445 shares of Series B Convertible Preferred Stock to the term loan lender at an original issuance price of \$0.2999 per share, for gross proceeds of \$1,000,000, which is included in the \$15,000,000 described above.

At any time after the initial offering of the Series B Convertible Preferred Stock and prior to the earlier of (i) an IPO, (ii) a deemed liquidation event, or (iii) June 30, 2017, certain participants in the Series B Convertible Preferred Stock equity offering may purchase up to an additional 53,351,117 shares of Series B Convertible Preferred Stock under the same terms and conditions of the initial offering. In the event of a second closing, if an eligible holder of Series B Convertible Preferred Stock does not participate at their full commitment, they are subject to a "pay to play" penalty whereby they would be required to convert each share of Series B Convertible Preferred Stock into 1/10th of a share of Common Stock.

The right of the investors (the "Investor Rights Obligation") to purchase Series B Convertible Preferred Stock represented a freestanding financial instrument and was indexed to an obligation of the Company to repurchase its Series B Convertible Preferred Stock by transferring assets. As such, the Company accounted for the Investor Rights Obligation as a liability in accordance with ASC 480. The Company adjusted the carrying value of the liability to its estimated fair value at each reporting date. Increases or decreases in the fair value of the Investor Rights Obligation were recorded as other income (expense) in the accompanying statement of operations. The fair value of the liability was determined using a valuation model, which considers the probability of achieving certain milestones, the entity's cost of capital, the estimated period the rights will be outstanding, consideration received for the instrument with the rights, the number of shares to be issued to satisfy the rights, the price of such shares and any changes in the fair value of the underlying instrument. At the date of issuance in July 2014, the Company recorded the Investor Rights Obligation at its initial estimated fair value of \$2,598,510 of which \$2,455,258 and \$143,252 were recorded as a reduction to the carrying of the

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)**

Series B Convertible Preferred Stock and term loan (see Note 9), respectively. The change in fair value of the Investor Rights Obligation was \$1,486,510 for the year ended December 31, 2014, and was recorded as other expense in the accompanying Statement of Operations.

The Company incurred \$442,948 in costs associated with issuing the Series B Convertible Preferred Stock of which \$26,921 was allocated to the Investor Rights Obligation and \$416,027 was recorded as a reduction to the carrying value of the Series B Convertible Preferred Stock.

***Common Stock Warrants***

During 2012, a total of 277,749 warrants to purchase shares of Common Stock at an exercise price equal to \$28.00 per share were issued to investors in connection with the issuance of the Company's Series A Convertible Preferred Stock, the conversion of the convertible demand promissory note and the amount due to related party. The warrants became exercisable at the grant date. In addition, a total of 126,091 warrants to purchase Common Stock at an exercise price equal to \$28.00 per share were issued to the placement agent. The Company determined the fair value of the warrants to be approximately \$2.80 per warrant. The fair value was calculated using a Black-Scholes pricing model using a fair market value of \$8.68 per share for its Common Stock and similar assumptions disclosed later in Note 11.

In August 2013, a total of 80,966 warrants to purchase shares of Common Stock at an exercise price now fixed at \$28.00 per share were issued to investors in connection with the Company's Series A-1 Convertible Preferred Stock. The warrants became exercisable at the grant date. In addition, a total of 24,306 warrants to purchase Common Stock at an exercise price equal to \$21.00 per share were issued to the placement agent. The fair value was calculated using a fair market value of \$8.96 per share for its Common Stock and similar assumptions disclosed in Note 4. The total fair value of the warrants issued to the placement agent on the date of grant was approximately \$72,000, recorded as offering costs. In addition, in the event a holder of the Company's Series A Convertible Preferred Stock purchased a number of shares of Series A-1 Convertible Preferred Stock in an amount equal to at least 40% of the shares of Series A Convertible Preferred Stock owned by such holder, the Company amended the warrant to purchase the Company's Common Stock by such holder received in connection with his, her or its purchase of shares of Series A Convertible Preferred Stock such that the exercise price per share of such warrant was reduced from \$28.00 to \$14.00. A total of 58,849 warrants were amended. This modification was recorded as a deemed dividend to the Preferred A holders in the amount of \$81,964.

In December 2013, a warrant to purchase 3,571 shares of Common Stock at an exercise price equal to \$28.00 per share was issued to a consulting firm which is assisting the Company in identifying commercial and strategic opportunities. The Company determined the fair value of the warrants to be approximately \$3.64 per warrant. The fair value was calculated using a Black-Scholes pricing model using a fair market value of \$10.08 per share for its Common Stock and similar assumptions disclosed later in Note 11.

In connection with the convertible promissory notes issued from April through June 2014, the holders received warrants to purchase 148,854 shares of the Company's Common Stock in the aggregate. The warrants are exercisable at the option of the holder at any time during their five-year



**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)**

term at a price per share at which equity securities are sold in a qualified financing event or offered to the public in the event of an IPO. Upon completing the Series B Convertible Preferred Stock equity offering on July 11, 2014, a qualified financing event occurred and the holders are eligible to exercise their warrants, at any time, at an exercise price of \$8.40 per share. In the event of an IPO, change in control or capital restructuring as set forth in the warrant, the Company will provide the warrant holders notification of such events to afford the holders the ability to exercise their warrants prior to the event. If the holders do not exercise his/her right, then the warrants shall expire in accordance with their terms. The exercise price of the warrants does not contain "down round" protection provisions.

Due to the variable exercise price at each issuance from April through June 2014, the warrants were classified as liabilities and subject to derivative accounting. On July 11, 2014, the exercise price was fixed and met the requirements for equity classification.

In July 2014, a warrant to purchase 17,863 shares of Common Stock at an exercise price equal to \$8.40 per share was issued to a consulting firm for advisory services. The Company determined the fair value of the warrants to be approximately \$2.52 per warrant. The fair value was calculated using a Black Scholes pricing model using a fair market value of \$5.32 per share for its Common Stock and similar assumptions disclosed later in Note 11.

In September 2014, a warrant to purchase 2,380 shares of Common Stock at an exercise price equal to \$8.68 per share was issued to a former member of the board of directors. The Company determined the fair value of the warrants to be approximately \$3.36 per warrant. The fair value was calculated using a Black-Scholes pricing model using a fair market value of \$5.32 per share for its Common Stock and similar assumptions disclosed later in Note 11.

At December 31, 2014, the following Common Stock warrants were outstanding:

<b>Number of shares underlying warrants issued to investors of Convertible Preferred Stock</b>	<b>Exercise price per share</b>	<b>Expiration Date</b>
109,997	\$ 28.00	February 2017
29,277	\$ 14.00	February 2017
90,550	\$ 28.00	March 2017
29,571	\$ 14.00	March 2017
130,234	\$ 28.00	April 2017
14,285	\$ 28.00	July 2017
80,966	\$ 28.00	August 2018
24,306	\$ 21.00	August 2018
3,571	\$ 28.00	December 2018
59,543	\$ 8.40	April 2019
23,817	\$ 8.40	May 2019
65,498	\$ 8.40	June 2019
17,863	\$ 8.40	July 2019
2,380	\$ 8.68	May 2022
<b>681,858</b>		

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)*****Series B Convertible Preferred Stock Warrants***

In August 2014, a warrant to purchase 625,208 shares of Series B Convertible Preferred Stock, at an exercise price equal to \$0.2999 per share, was issued to the term loan lender in conjunction with the loan of \$7.5 million (see Note 9). The fair value was calculated at \$115,056 using a Black-Scholes pricing model using a fair market value of \$0.25 per share for its Series B Convertible Preferred Stock and similar assumptions disclosed later in Note 11.

**11. STOCK-BASED COMPENSATION*****2011 Stock Incentive Plan***

On April 28, 2011, the board of directors adopted the Plan reserving and authorizing up to 178,571 shares of Common Stock for stock-based compensation awards to attract, retain and reward eligible employees, consultants, and non-employee directors. The options have a contractual term of ten years. Generally, the options vest annually over three or four years, as determined by the board of directors, upon each option grant, although certain option grants in 2014 were fully vested on the grant date. On January 10, 2012, the board of directors and stockholders of the Company approved an amendment to the Plan authorizing an increase in the aggregate number of shares reserved for issuance under the Plan from 178,571 to 285,714 shares of Common Stock. On May 6, 2013, the board of directors approved an amendment to the Plan authorizing an increase in the aggregate number of shares reserved for issuance under the Plan from 285,714 to 704,428 shares of Common Stock. As of December 31, 2014, there were 212,383 shares remaining under the Plan available for future issuance.

On May 8, 2012, the board of directors approved three grants of non-qualified stock options outside of the Plan aggregating 167,857 to the President and Chief Executive Officer and two non-employee directors of the Company at \$8.68 per share, one-third vesting on three consecutive annual anniversaries.

The estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized was as follows:

	Year Ended December 31, 2013	Year Ended December 31, 2014
Research and development	\$ 165,724	\$ 201,653
General and administrative	582,924	884,928
Total stock-based compensation	<u>\$ 748,648</u>	<u>\$ 1,086,581</u>

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**11. STOCK-BASED COMPENSATION (Continued)**

A summary of option activity is as follows:

	Options Outstanding			Weighted Average Remaining Contractual Term (in years)
	Number of Shares	Weighted-Average Exercise Price	Fair Value Of Options Granted	
Balance, December 31, 2013	381,669	\$ 7.78		8.39
Granted	177,484	\$ 12.14	\$ 389,538	
Forfeitures	(6,427)	\$ 8.68		
Balance, December 31, 2014	552,726	\$ 9.17		8.17
Vested or expected to vest at December 31, 2014	552,726	\$ 9.17		8.17
Exercisable at December 31, 2014	440,442	\$ 9.26		7.72

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's Common Stock for those stock options that had exercise prices lower than the fair value of the Company's Common Stock. As of December 31, 2014, the aggregate intrinsic value of options outstanding and vested and expected to vest were \$22,000.

The per-share weighted-average fair value of the options granted during 2013 and 2014 was estimated at \$5.60 and \$2.24, respectively, on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2013	2014
Risk-free interest rate	0.85 - 1.90%	0.85 - 1.97%
Expected term of options (in years)	6.0	5.0 - 6.25
Expected stock price volatility	70.0%	70.0%
Expected annual dividend yield	0.00%	0.00%

The valuation assumptions were determined as follows:

- Risk-free interest rate: The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- Expected term of options: The Company estimates the expected life of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin No. 107, whereby, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data.
- Expected stock price volatility: The Company estimated the expected volatility based on actual historical volatility of the stock price of other publicly-traded biotechnology companies engaged in lines of business that are the same or similar to the Company's. The Company calculated the

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****11. STOCK-BASED COMPENSATION (Continued)**

historical volatility of the selected companies by using daily closing prices over a period of the expected term of the associated award. The companies were selected based on their enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the associated award. A decrease in the selected volatility would decrease the fair value of the underlying instrument.

- **Expected annual dividend yield:** The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed and expected dividend yield of 0.0%.

The Company considered numerous objective and subjective factors in the assessment of fair value of its Common Stock, including the price for the Company's Series A Convertible Preferred Stock that was sold to investors and the rights, preferences and privileges of the Series A Convertible Preferred Stock and Common Stock, the Company's financial condition and results of operations during the relevant periods, including the status of the development of the Company's product candidates, and the status of strategic initiatives. These estimates involve a significant level of judgment.

As of December 31, 2014, there was \$0.2 million of total unrecognized compensation expense, related to unvested options granted under the Plan, unvested options granted outside of the Plan, and restricted stock to be recognized as follows:

<u>Year ending December 31,</u>	
2015	\$ 175,312
2016	24,493
2017	942
2018	79
	<u>\$ 200,826</u>

***Restricted Stock***

During July and August of 2011 certain issuances of Common Stock totaling 14,285 shares, originally issued in April 2011 to non-employees, were modified as restricted stock and are subject to a three year vesting period. The modification resulted in \$41,000 and \$24,000 of additional research and development expense recorded for the years ended December 31, 2013 and 2014, respectively. There were no issuances or forfeitures of restricted during the years ended December 31, 2013 and 2014. There were 3,571 and 7,142 restricted that vested during the comparable periods. As of December 31, 2014, all restricted shares are fully vested.

**12. INCOME TAXES**

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****12. INCOME TAXES (Continued)**

realized. The Company recognized no material adjustment for unrecognized income tax benefits. Through December 31, 2014, the Company had no unrecognized tax benefits or related interest and penalties accrued.

The significant components of the Company's deferred tax assets are comprised of the following:

	<u>December 31,</u>	
	<u>2013</u>	<u>2014</u>
Deferred tax assets:		
Net operating losses	\$ 9,031,629	\$ 16,113,309
Research and development credits	1,040,789	1,640,277
Deferred rent	9,339	17,844
Accrued compensation	58,142	31,060
Stock compensation	906,923	1,349,899
Basis difference in tangible and intangible assets	596,003	340,570
Total deferred tax assets	11,642,825	19,492,959
Less valuation allowance	(11,642,825)	(19,492,959)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

For the year ended December 31, 2014, the Company increased the valuation allowance by \$7.9 million to fully reserve for the value of deferred tax assets. Due to continued operating losses, there is no indication that it is more likely than not that the Company will be able to utilize its deferred tax assets.

As of December 31, 2014 the Company had \$40,850,000 of Federal and Maryland net operating loss ("NOL") carryforwards that will begin to expire in 2031. As of December 31, 2014 the Company had \$1,143,000 and \$497,000 of Maryland and federal research and development credits, respectively, that will begin to expire in 2018. The NOL and research and development credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs and research and development credits that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. All of our tax years are currently open to examination by each tax jurisdiction in which the Company is subject to taxation.

**CERECOR INC.****Notes to Financial Statements (Continued)****As of and for the Years Ended December 31, 2014 and 2013****12. INCOME TAXES (Continued)**

A reconciliation of income tax expense computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	<u>December 31,</u>	
	<u>2013</u>	<u>2014</u>
Federal Statutory Rate	34.00%	34.00%
Permanent Differences	(0.03)%	(0.02)%
Warrants	(0.31)%	4.80%
State Taxes	7.87%	7.22%
Research and Development Credit	4.90%	2.75%
Other	0%	0.15%
Change in valuation allowance	<u>(46.43)%</u>	<u>(48.90)%</u>
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>

**13. COMMITMENTS AND CONTINGENCIES*****Offer Letters***

The Company has entered into offer letters with certain of its executives. The letters provide for, among other things, salary, bonus and severance payments.

***Office Lease***

In August 2013, the Company entered into a lease for new corporate office space location in Baltimore, Maryland. The lease provides for three months of rent abatement and includes escalating rent payments. Rent expense is recognized on a straight-line basis over the term of the lease. During 2014 rent expense amounted to approximately \$192,000. Pursuant to the terms of such lease, the Company's future lease obligation is as follows:

<u>Year ending December 31,</u>	
2015	\$ 147,384
2016	151,068
2017	154,845
2018	158,716
	<u>\$ 612,013</u>

**14. SUBSEQUENT EVENTS**

The Company has completed an evaluation of all subsequent events through April 29, 2015, the date on which these financial statements were available to be issued, to ensure that these financial statements include appropriate disclosure of events both recognized in the financial statements as of December 31, 2014 and events which occurred subsequently but were not recognized in the financial statements.

**CERECOR INC.**

**Notes to Financial Statements (Continued)**

**As of and for the Years Ended December 31, 2014 and 2013**

**14. SUBSEQUENT EVENTS (Continued)**

In February 2015, the Company entered into an exclusive license agreement with Eli Lilly and Company ("Lilly") pursuant to which Lilly granted the Company rights relating to certain small molecule compounds, which are potent and selective kappa opioid receptor antagonists. In consideration of the license, the Company is required to make an initial payment totaling \$1,000,000. Pursuant to the license agreement, the Company paid \$750,000 to Lilly within 30 days of the execution of the license, and, upon receipt of certain preclinical data, the Company will pay an additional \$250,000. The initial payment of \$750,000 will be recorded as research and development expense. Additional payments may be due upon achievement of development and regulatory milestones, including first commercial sale. Upon commercialization, the Company is obligated to pay Lilly milestones and royalties on net sales.

***Reverse Stock Split***

On June 26, 2015, the Company's board of directors approved a one-for-28 reverse stock split of the Company's Common Stock. As a result of the reverse stock split, (i) each 28 shares of then-outstanding Common Stock was reduced to one share of Common Stock; (ii) the number of shares of Common Stock into which each then-outstanding share of our Series A, A-1 and B Convertible Preferred Stock and our then-outstanding warrants or options to purchase shares of Common Stock are convertible or exercisable into, was proportionately reduced; and (iii) the exercise price of each then-outstanding warrant or option to purchase shares of Common Stock was proportionately increased. Fractional shares resulting from the reverse stock split have been rounded down to the next whole share and in lieu of any fractional shares the Company will pay a cash amount to the holder of such fractional share equal to the fair market value of such fractional share as determined by the Company's board of directors. On September 1, 2015, the Company filed an amendment to its amended and restated certificate of incorporation effecting such reverse stock split. All share and per share amounts of common stock in the accompanying financial statements have been restated for all periods to give retroactive effect to the reverse stock split. The shares of common stock retained a par value of \$0.001 per share. Accordingly, the stockholders' deficit reflects the reverse stock split by reclassifying from Common Stock to Additional paid-in capital in an amount equal to the par value of the decreased shares resulting from the reverse stock split.

***Amended Certificate of Incorporation***

On September 1, 2015, the Company filed an amendment to its amended and restated certificate of incorporation to give effect to the reverse stock split and revised the definition of a Qualified Public Offering so that the Preferred Stock will automatically convert upon the closing of the sale of shares of Common Stock to the public in an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended.

**CERECOR INC.**

**Balance Sheets**

	<b>December 31, 2014</b>	<b>June 30, 2015 (unaudited)</b>	<b>Pro Forma June 30, 2015 (unaudited)</b>
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 11,742,349	\$ 6,142,864	\$ 6,142,864
Prepaid expenses and other current assets	360,307	104,357	104,357
Restricted cash—current portion	58,333	58,333	58,333
Total current assets	12,160,989	6,305,554	6,305,554
Restricted cash, net of current portion	117,165	117,165	117,165
Deferred financing costs	—	1,131,699	1,131,699
Property and equipment, net	38,740	27,702	27,702
Total assets	<u>\$ 12,316,894</u>	<u>\$ 7,582,120</u>	<u>\$ 7,582,120</u>
<b>Liabilities, convertible preferred stock and stockholders' (deficit) equity</b>			
Current liabilities:			
Current portion of long term debt, net of discount	\$ 1,905,879	\$ 3,043,529	\$ 3,043,529
Accounts payable	931,139	1,246,546	1,246,546
Accrued expenses and other current liabilities	975,114	1,521,653	1,521,653
Warrant liability	69,684	94,222	—
Investor rights obligation	1,112,000	1,425,201	—
Total current liabilities	4,993,816	7,331,151	5,811,728
Long term debt, net of current portion and discount	5,308,211	4,009,435	4,009,435
Other long term liability	—	84,918	84,918
Total liabilities	10,302,027	11,425,504	9,906,081
Convertible preferred stock:			
Series A—\$0.001 par value; 31,116,391 shares authorized, issued and outstanding at December 31, 2014 and June 30, 2015 and no shares issued and outstanding at June 30, 2015 (pro forma) (aggregate liquidation preference of \$23,337,293 at June 30, 2015)	10,462,885	10,462,885	—
Series A-1—\$0.001 par value; 9,074,511 shares authorized, issued and outstanding at December 31, 2014 and June 30, 2015 and no shares issued and outstanding at June 30, 2015 (pro forma) (aggregate liquidation preference of \$6,805,883 at June 30, 2015)	3,389,331	3,389,331	—
Series B—\$0.001 par value; 115,000,000 shares authorized at December 31, 2014 and June 30, 2015; 58,948,735 shares issued and outstanding at December 31, 2014 and June 30, 2015 and no shares issued and outstanding at June 30, 2015 (pro forma) (aggregate liquidation preference of \$17,678,725 at June 30, 2015)	14,493,315	14,493,315	—
Total convertible preferred stock	28,345,531	28,345,531	—
Stockholders' (deficit) equity:			
Common Stock—\$0.001 par value; 230,000,000 shares authorized at December 31, 2014 and June 30, 2015; 649,721 shares issued and outstanding at December 31, 2014 and June 30, 2015 and 230,000,000 shares authorized and 4,630,143 shares issued and outstanding at June 30, 2015 (pro forma)	650	650	4,630
Additional paid-in capital	16,742,063	17,034,276	46,895,250
Accumulated deficit	(43,073,377)	(49,223,841)	(49,223,841)
Total stockholders' deficit	(26,330,664)	(32,188,915)	(2,323,961)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 12,316,894</u>	<u>\$ 7,582,120</u>	<u>\$ 7,582,120</u>

See accompanying notes to unaudited financial statements.



**CERECOR INC.****Unaudited Statements of Operations**

	Six Months Ended	
	June 30,	
	2014	2015
Operating expenses:		
Research and development	\$ 5,610,764	\$ 3,598,606
General and administrative	1,673,573	1,776,817
Loss from operations	<u>(7,284,337)</u>	<u>(5,375,423)</u>
Other income (expense):		
Change in fair value of warrant liability and Investor Rights Obligation	385,990	(337,739)
Interest expense, net	<u>(794,038)</u>	<u>(437,302)</u>
Total other income (expense)	<u>(408,048)</u>	<u>(775,041)</u>
Net loss	<u>\$ (7,692,385)</u>	<u>\$ (6,150,464)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (12.10)</u>	<u>\$ (9.47)</u>
Weighted-average shares of Common Stock outstanding, basic and diluted	<u>635,714</u>	<u>649,721</u>
Pro forma net loss per share of Common Stock—basic and diluted		<u>\$ (1.33)</u>
Pro forma weighted-average shares of Common Stock outstanding, basic and diluted		<u>4,630,143</u>

See accompanying notes to unaudited financial statements.

## CERECOR INC.

## Unaudited Statement of Convertible Preferred Stock and Stockholders' Deficit

For the Period from January 1, 2015 to June 30, 2015

	Series A, A-1 and B Convertible Preferred Stock		Stockholders' Deficit				
			Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount			
<b>Balance, January 1, 2015</b>	99,139,637	\$ 28,345,531	649,721	\$ 650	\$ 16,742,063	\$ (43,073,377)	\$ (26,330,664)
Stock-based compensation	—	—	—	—	292,213	—	292,213
Net Loss	—	—	—	—	—	(6,150,464)	(6,150,464)
<b>Balance, June 30, 2015</b>	<u>99,139,637</u>	<u>\$ 28,345,531</u>	<u>649,721</u>	<u>\$ 650</u>	<u>\$ 17,034,276</u>	<u>\$ (49,223,841)</u>	<u>\$ (32,188,915)</u>

See accompanying notes to unaudited financial statements.

**CERECOR INC.****Unaudited Statements of Cash Flows**

	Six Months Ended June 30,	
	2014	2015
<b>Operating activities</b>		
Net loss	\$ (7,692,385)	\$ (6,150,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	13,665	11,038
Stock-based compensation expense	481,303	292,213
Non-cash interest expense	794,627	91,809
Change in fair value of warrant liability and Investor Rights Obligation	(385,990)	337,739
Changes in assets and liabilities:		
Prepaid expenses and other assets	199,663	255,950
Restricted cash	(350)	—
Accounts payable	1,061,356	(3,478)
Accrued expenses and other liabilities	1,077,464	364,958
Net cash used in operating activities	<u>(4,450,657)</u>	<u>(4,800,235)</u>
<b>Financing activities</b>		
Proceeds from issuance of convertible notes	1,250,000	—
Principal payments on venture debt	—	(252,934)
Deferred financing costs	—	(546,316)
Net cash provided by (used in) financing activities	<u>1,250,000</u>	<u>(799,250)</u>
Decrease in cash and cash equivalents	(3,200,647)	(5,599,485)
Cash and cash equivalents at beginning of period	3,421,480	11,742,349
Cash and cash equivalents at end of period	<u>\$ 220,833</u>	<u>\$ 6,142,864</u>
<b>Supplemental disclosures of cash flow information</b>		
Cash paid for interest	<u>\$ —</u>	<u>\$ 298,106</u>
<b>Supplemental disclosures of noncash financing activities</b>		
Accrued deferred financing costs	<u>\$ 464,863</u>	<u>\$ 585,383</u>

See accompanying notes to unaudited financial statements.

**CERECOR INC.**

**Notes to Unaudited Financial Statements**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015**

**1. BUSINESS**

***Description of Business and Organization***

Cerecor Inc. (the "Company" or "Cerecor") was incorporated on January 31, 2011 in Delaware as Ceregen Corporation and subsequently changed the name to Cerecor Inc. in March 2011. The Company is a clinical-stage biopharmaceutical company with the goal of becoming a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric disorders. The Company's operations since inception have been limited to organizing and staffing the Company, acquiring rights to and developing certain product candidates and its product platform, business planning and raising capital.

***Liquidity***

The Company's financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should the Company be unable to continue to fund its operations. The Company has not generated any product revenues and has not yet achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and if achieved, could be sustained on a continuing basis.

The Company has incurred recurring operating losses since inception. For the six months ended June 30, 2015, the Company incurred a net loss of \$6,150,464 and generated negative cash flows from operations of \$4,800,235. As of June 30, 2015, the Company had an accumulated deficit of \$49,223,841. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to the clinical development of its product candidates, its product platform, its preclinical programs, business development and the development of its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy. To fully execute its business plan, the Company will need to complete certain research and development activities, have positive clinical trial results and obtain marketing approval for its product candidates, which may span many years, and may ultimately be unsuccessful. Any delays in completing these activities or negative clinical trial results could adversely impact the Company. The Company plans to meet its capital requirements primarily through a combination of equity and debt financings, collaborations, strategic alliances and marketing distribution or licensing arrangements and in the longer term, revenue from product sales to the extent its product candidates receive marketing approval and are commercialized. There can be no assurance, however, that the Company will be successful in obtaining financing at the level needed to sustain operations and develop its product candidates or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow. The Company currently anticipates that its cash and cash equivalents will be sufficient to meet its anticipated cash requirements through at least the end of the third quarter of 2015. These factors raise significant doubt about the Company's ability to continue as a going concern.

**CERECOR INC.**

**Notes to Unaudited Financial Statements (Continued)**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015**

**2. SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

The Company's unaudited financial statements have been prepared in accordance with U. S. generally accepted accounting principles ("GAAP"). In the opinion of management, the accompanying unaudited financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations and cash flows. The balance sheet at December 31, 2014 has been derived from audited financial statements at that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the United States Securities and Exchange Commission ("SEC"). The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited financial statements are read in conjunction with the December 31, 2014 audited financial statements.

***Unaudited Pro Forma Presentation***

On December 17, 2013, the Company's board of directors authorized management of the Company to confidentially submit a registration statement to the SEC for the Company to sell shares of its Common Stock (the "Common Stock") to the public. The unaudited pro forma balance sheet information as of June 30, 2015 assumes the conversion of all outstanding shares of the Company's Series A Convertible Preferred Stock, Series A-1 Convertible Preferred Stock and Series B Convertible Preferred Stock (collectively, "Preferred Stock") as of that date into shares of the Company's Common Stock in connection with a qualified initial public offering ("IPO") (see Note 8). The unaudited pro forma net loss per share is computed using the weighted-average number of shares of Common Stock outstanding and gives effect to the automatic conversion of all outstanding shares of the Company's Preferred Stock into an aggregate of 3,980,422 shares of the Company's Common Stock as of January 1, 2015 or the date of original issuance, if later.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, other comprehensive income and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to clinical trial accruals, Investor Rights Obligation (see Note 8), and warrant liability. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

In addition, the Company utilizes estimates and assumptions in determining the fair value of its Common Stock. The Company granted stock options at exercise prices not less than the fair value of its Common Stock as determined by the board of directors, with input from management. Management uses the assistance of a third-party valuation firm in estimating the fair value of the Common Stock. The board of directors has determined the estimated fair value of the Common Stock based on a number of objective and subjective factors, including external market conditions affecting the

**CERECOR INC.**

**Notes to Unaudited Financial Statements (Continued)**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

biotechnology industry sector and the historic prices at which the Company sold shares of its Preferred Stock.

***Deferred Offering Costs***

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs (non-current) until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the equity financing for which those costs relate no longer be considered probable of being consummated, all deferred offering costs will be charged to operating expenses in the statement of operations at such time. The Company has incurred and deferred offering costs of \$1,131,699 during the six months ended June 30, 2015. We will incur additional offering costs during the third quarter in anticipation of an initial public offering.

***Net Loss Per Share of Common Stock, Basic and Diluted***

Basic net loss per share of Common Stock is computed by dividing net loss by the weighted-average number of shares of Common Stock outstanding during the period, excluding the dilutive effects of Preferred Stock, Investor Rights Obligation, warrants on Preferred Stock and Common Stock, stock options and unvested restricted stock. Diluted net loss per share of Common Stock is computed by dividing the net loss by the sum of the weighted-average number of shares of Common Stock outstanding during the period plus the potential dilutive effects of warrants on Common Stock, stock options and unvested restricted stock outstanding during the period calculated in accordance with the treasury stock method, although these shares and options are excluded if their effect is anti-dilutive. In addition, the Company analyzes the potential dilutive effect of the outstanding Preferred Stock, Investor Rights Obligation, and warrants on Preferred Stock under the "if-converted" method when calculating diluted earnings per share, in which it is assumed that the outstanding security converts into Common Stock at the beginning of the period. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted net loss per share of Common Stock for the six months ended June 30, 2014 and 2015.

**CERECOR INC.****Notes to Unaudited Financial Statements (Continued)****As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015****2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

The following outstanding securities at June 30, 2014 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	June 30, 2014	June 30, 2015
Series A Convertible Preferred Stock	31,116,391	31,116,391
Series A-1 Convertible Preferred Stock	9,074,511	9,074,511
Series B Convertible Preferred Stock	—	58,948,735
Common Stock dividends on Series A-1 Convertible Preferred Stock	6,861	—
Unvested restricted stock	7,142	—
Stock options	425,263	510,884
Warrants on Common Stock	661,673	657,474
Warrants on Preferred Stock	—	625,208
Investor Rights Obligation	—	53,351,117

***Income Taxes***

The Company accounts for income taxes under the asset and liability method in accordance with ASC 740, *Income Taxes* ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. A full valuation allowance has been established against all of the deferred tax assets as it is more likely than not that these assets will not be realized given the Company's history of operating losses. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position.

The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of June 30, 2015, the Company does not believe any material uncertain tax positions are present.

***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue From Contracts With Customers* ("ASU 2014-09"). Pursuant to this update an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The amendments in this update are currently effective for annual reporting periods beginning after December 15, 2016, including interim periods within that

**CERECOR INC.**

**Notes to Unaudited Financial Statements (Continued)**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
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**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

reporting period and are to be applied retrospectively, or on a modified retrospective basis. Early application is not permitted. In July 2015, the FASB approved a one-year deferral of the effective date for annual reporting periods beginning after December 15, 2017 with early adoption permitted for annual reporting periods beginning after December 15, 2016.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard, but believes its adoption will have no impact on its financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. The guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The standard also aligns the GAAP presentation with International Financial Reporting Standards and will remedy the long-standing conflict with the guidance in FASB Concepts Statement No. 6, *Elements of Financial Statements*, which indicates that debt issuance costs do not meet the definition of an asset, because they provide no future economic benefit. The standard is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis. The adoption of this guidance during the six months ended June 30, 2015 did not have a material impact on the Company's balance sheets.

**3. FAIR VALUE MEASUREMENTS**

ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.



CERECOR INC.

Notes to Unaudited Financial Statements (Continued)

As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015

3. FAIR VALUE MEASUREMENTS (Continued)

At December 31, 2014 and June 30, 2015, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts payable, accrued expenses and other current liabilities, long term debt, Warrant Liability and the Investor Rights Obligation. The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, restricted cash, accounts payable, and accrued expenses and other current liabilities approximate their respective fair values because of the short-term nature of these accounts. The estimated fair value of the Company's debt of \$7.0 million as of June 30, 2015 was based on current interest rates for similar types of borrowings and is in Level Two of the fair value hierarchy.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities that are measured at fair value on a recurring basis:

	December 31, 2014		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets</b>			
Investments in money market funds*	\$ 11,251,724	\$ —	\$ —
<b>Liabilities</b>			
Investor Rights Obligation	\$ —	\$ —	\$ 1,112,000
Warrant Liability	\$ —	\$ —	\$ 69,684

	June 30, 2015		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets</b>			
Investments in money market funds*	\$ 5,773,250	\$ —	\$ —
<b>Liabilities</b>			
Investor Rights Obligation	\$ —	\$ —	\$ 1,425,201
Warrant Liability	\$ —	\$ —	\$ 94,222

\* Investments in money market funds are reflected in cash and cash equivalents on the accompanying Balance Sheets.

**Level 3 Valuation**

The Warrant Liability (which relates to warrants to purchase shares of Series B Convertible Preferred Stock) is marked-to-market each reporting period with the change in fair value recorded to

**CERECOR INC.****Notes to Unaudited Financial Statements (Continued)****As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015****3. FAIR VALUE MEASUREMENTS (Continued)**

other income (expense) in the Statements of Operations until the warrants are exercised, expire or other facts and circumstances lead the Warrant Liability to be reclassified to stockholders' equity. The fair value of the Warrant Liability is estimated using a Black-Scholes Option Pricing Model. The significant assumptions used in preparing the option pricing model for valuing the Warrant Liability as of December 31, 2014 include (i) volatility of 60.0%, (ii) risk free interest rate of 2.1%, (iii) strike price (\$0.2999), (iv) fair value of Series B Convertible Preferred Stock (\$0.18), and (v) expected life of 8.23 years. The significant assumptions used in preparing the option pricing model for valuing the Warrant Liability as of June 30, 2015 include (i) volatility of 70.0%, (ii) risk free interest rate of 1.85%, (iii) strike price (\$0.2999), (iv) fair value of Series B Convertible Preferred Stock (\$0.21), and (v) expected life of 6.0 years. Significant decreases in the Company's stock price volatility will significantly decrease the overall valuation of the Company's warrant liability, while significant increases in the Company's stock price volatility will significantly increase the overall valuation.

The Investor Rights Obligation will expire at the earlier of (i) an IPO, (ii) a deemed liquidation event, or (iii) June 30, 2017. While outstanding, the Investor Rights Obligation is remeasured at each reporting period and changes in fair value are recorded as a component of other income (expense) in the Company's Statement of Operations. The fair value of the Investor Rights Obligation was determined using a valuation model, which considers the probability of achieving certain milestones, the entity's cost of capital, the estimated period the rights will be outstanding, consideration received for the instrument with the rights, the number of shares to be issued to satisfy the rights, the price of such shares and any changes in the fair value of the underlying instrument. The significant assumptions used in preparing the option pricing model for valuing the Company's Investor Rights Obligation as of December 31, 2014 include (i) volatility (60.0%), (ii) risk free interest rate ranging from 0.05% to 0.63%, (iii) strike price (\$0.2999), (iv) fair value of Preferred Stock ranging from \$0.00 to \$0.18, and (v) expected life ranging from 0.5 to 1.75 years. The significant assumptions used in preparing the option pricing model for valuing the Company's Investor Rights Obligation as of June 30, 2015 include (i) volatility of 70%, (ii) risk free interest rate ranging from 0.03% to 0.40%, (iii) strike price (\$0.2999), (iv) fair value of Preferred Stock ranging from \$0.09 to \$0.29, and (v) expected life ranging from 0.27 to 1.25 years. Significant decreases in the the price per share of the Company's Series B Convertible Preferred Stock and stock price volatility will significantly decrease the overall valuation of its Investor Rights Obligation, while significant increases will significantly increase the overall valuation.

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the Warrant Liability and the Investor Rights Obligation for the six months ended June 30, 2015:

	<u>Warrant Liability</u>	<u>Investor Rights Obligation</u>	<u>Total</u>
Balance at December 31, 2014	\$ 69,684	\$ 1,112,000	\$ 1,181,684
Change in fair value	24,538	313,201	337,739
Balance at June 30, 2015	<u>\$ 94,222</u>	<u>\$ 1,425,201</u>	<u>\$ 1,519,423</u>

**CERECOR INC.****Notes to Unaudited Financial Statements (Continued)****As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015****3. FAIR VALUE MEASUREMENTS (Continued)**

No other changes in valuation techniques or inputs occurred during the six months ended June 30, 2014 and 2015. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the six months ended June 30, 2014 and 2015.

**4. DEFERRED FINANCING COSTS**

Deferred financing costs incurred in preparation for an IPO consisted of the following:

	<u>December 31, 2014</u>	<u>June 30, 2015</u>
Legal fees	\$ 525,414	\$ 629,230
Accounting fees	435,410	392,950
Printing costs	103,282	109,519
Expense upon determination that consummation of offering is not probable	(1,064,106)	—
Total deferred financing costs	<u>\$ —</u>	<u>\$ 1,131,699</u>

**5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES**

Accrued expenses and other current liabilities consisted of the following:

	<u>December 31, 2014</u>	<u>June 30, 2015</u>
Compensation and benefits	\$ 129,450	\$ 276,492
Research and development expenses	598,883	717,322
General and administrative	159,045	479,828
Accrued interest	87,736	48,011
Total accrued expenses and other current liabilities	<u>\$ 975,114</u>	<u>\$ 1,521,653</u>

**6. ASSET ACQUISITION AND LICENSE AGREEMENTS**

In February 2015, the Company acquired rights to CERC-501, which was previously referred to as OpRA Kappa, through an exclusive, worldwide license from Eli Lilly and Company. CERC-501 is a high-binding, selective Kappa opioid receptor ("KOR") antagonist. Pursuant to the license agreement, the Company paid \$750,000 to Lilly within 30 days of the execution of the license agreement, which was recorded as research and development expense in the accompanying unaudited Statement of Operations for the six months ended June 30, 2015. Upon the Company undertaking a 9-month toxicology study in non-human primates and delivering a final study report, the Company will be required to pay Lilly an additional \$250,000. During the three months ended June 30, 2015, the Company determined that it would undertake this study and, as a result, the Company accrued \$250,000. Additional payments may be due upon achievement of development and regulatory milestones, including the first commercial sale. Upon commercialization, the Company is obligated to pay Lilly milestones and royalties on net sales.

**CERECOR INC.****Notes to Unaudited Financial Statements (Continued)**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015**

**6. ASSET ACQUISITION AND LICENSE AGREEMENTS (Continued)**

For the first KOR product the Company develops, the Company is required to make milestone payments in an amount not to exceed, in the aggregate, \$19,000,000 upon the achievement of various development and regulatory milestones, including first commercial sale. Additionally, the Company will be required to make sales milestone payments in an amount not to exceed \$30,000,000. Upon commercialization of a KOR product, we will pay Eli Lilly a tiered royalty percentage on net sales of a KOR product from mid-single digits to low-double digits. The royalty obligation will be on a product by product and country by country basis until the later of (i) the expiration of the last to expire valid patent claim of a patent licensed to us under the license agreement covering the KOR product in such country, or (ii) eleven years from the first commercial sale of the KOR product in such country.

The Company accounted for this transaction as an asset acquisition because it only acquired the assigned rights and technology and did not acquire any processes or activities.

**7. DEBT**

Debt consisted of the following:

	December 31, 2014	June 30, 2015
Term loan	\$ 7,500,000	\$ 7,247,065
Less: debt discount	(285,910)	(194,101)
Term Loan, net of debt discount	7,214,090	7,052,964
Less: current portion, net of debt discount	(1,905,879)	(3,043,529)
Long term debt, net of current portion and debt discount	<u>\$ 5,308,211</u>	<u>\$ 4,009,435</u>

**Term Loan**

In August 2014, the Company received a \$7,500,000 secured term loan from a finance company. The loan is secured by a lien on all of the Company's assets, excluding intellectual property, which was subject to a negative pledge. The loan contains certain additional nonfinancial covenants. In connection with the loan agreement, the Company's cash and investment accounts are subject to account control agreements with the finance company that give the finance company the right to assume control of the accounts in the event of a loan default. Loan defaults are defined in the loan agreement and include, among others, the finance company's determination that there is a material adverse change in the Company's operations. Interest on the loan is at a rate of the greater of 7.95%, or 7.95% plus the prime rate as reported in The Wall Street Journal minus 3.25%. The current interest rate is 7.95%. The loan was interest-only for nine months, and is repayable in equal monthly payments of principal and interest of \$304,278 over 27 months beginning in June 2015. Interest expense, which includes amortization of discount and the accrual of a termination fee, was approximately \$437,000 for the six months ended June 30, 2015 in the accompanying unaudited Statement of Operations.

In connection with the term loan, the Company issued a warrant to purchase 625,208 shares of Series B Convertible Preferred Stock at an exercise price of \$0.2999 per share that is exercisable for a period ending upon the earlier of ten years from the date of issuance and five years following an IPO.

**CERECOR INC.**

**Notes to Unaudited Financial Statements (Continued)**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015**

**7. DEBT (Continued)**

Upon the closing of an initial public offering, these warrants will become a warrant to purchase 22,328 shares of Common Stock at an exercise price of \$8.40, in accordance with its terms. The Company's warrant to purchase shares of Series B Convertible Preferred Stock represented a freestanding financial instrument that was indexed to an obligation of the Company to repurchase its Series B Convertible Preferred Stock by transferring assets and, therefore, met the criteria to be classified as a liability under FASB ASC 480, *Distinguishing Liabilities from Equity*. The Company records the warrant liability at its fair value using the Black-Scholes option pricing model and revalues the warrant at each reporting date (see Note 3).

***Convertible Promissory Notes***

From April through June 2014, the Company entered into several convertible promissory notes for aggregate proceeds of \$1.25 million. The loans bore interest at an annual rate of 6.0% and were to mature within 12 months from their issuance date. In the event that the Company completed a qualified equity offering that generated aggregate proceeds of at least \$10 million, the notes would automatically convert into the shares issued in connection with the qualified equity offering and at a conversion price equal to 75% of the qualified equity offering price. In the event that an equity offering did not occur by the maturity date, all interest and principal would have become due. The notes converted on July 11, 2014 when the Series B Convertible Preferred Stock equity offering was completed. The principal amount of the notes, and interest of \$9,016, was converted at 75% of the Series B Convertible Preferred Stock original issuance price, or \$0.22492 per share, and the Company issued 5,597,618 shares of Series B Convertible Preferred Stock.

In connection with issuing the notes, the holders received warrants to purchase 148,854 shares of the Company's Common Stock. The warrants are exercisable at the option of the holder at any time during their five-year term at a price per share at which equity securities are sold in a qualified financing event or offered to the public in the event of an IPO. Upon completing the Series B Convertible Preferred Stock equity offering on July 11, 2014, a qualified financing event occurred and the holders are eligible to exercise their warrants, at any time through their five-year terms, at an exercise price of \$8.40 per share. In the event of an IPO, change in control or capital restructuring, as set forth in the warrant, the Company will provide the holders of the warrants notification of such events to afford the holders the ability to exercise their warrants prior to the event. If the holder does not exercise the warrant, then the warrants shall expire in accordance with their terms. The exercise price of the warrants does not contain "down round" protection provisions.

Due to the variable exercise price and number of shares underlying the warrant prior to the completion of the qualified financing, the warrants were originally classified as liabilities and subject to derivative accounting. On July 11, 2014, the exercise price and number of shares underlying the warrant were fixed and the warrants were reclassified to permanent equity. At the time of the reclassification, the warrants had a fair value of \$379,000.

***Demand Notes***

On July 3, 2014, the Company issued \$999,666 in demand notes that were converted on July 11, 2014 upon completing the Series B Convertible Preferred Stock equity offering. The demand note

**CERECOR INC.**

**Notes to Unaudited Financial Statements (Continued)**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015**

**7. DEBT (Continued)**

holders were the majority participants in the Series B Convertible Preferred Stock equity offering. The purpose of the notes were to provide short term financing between the targeted closing date of Series B Convertible Preferred Stock equity offering, July 3, 2014, and the actual closing date of July 11, 2014. The demand notes converted at the original issuance price of Series B Convertible Preferred Stock of \$0.2999 per share, and the holders received 3,333,331 shares of Series B Convertible Preferred Stock (see Note 8). Interest at 0.31% was not paid due to the short term that the notes were outstanding.

**8. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**

At June 30, 2015, the Company was authorized to issue two classes of stock, Common Stock and Preferred Stock. The total number of shares of capital stock the Company was authorized to issue was 163,405,187 of which 8,214,285 was Common Stock and 155,190,902 was Preferred Stock. All shares of Common and Preferred Stock have a par value of \$0.001 per share. 31,116,391 of the authorized shares of Preferred Stock are designated as Series A Convertible Preferred Stock, 9,074,511 of the authorized shares of Preferred Stock are designated as Series A-1 Convertible Preferred Stock and the remaining 115,000,000 shares have been designated as Series B Convertible Preferred Stock.

Each share of Series A Convertible Preferred Stock will be convertible into 0.04464 shares of Common Stock, each share of Series A-1 Convertible Preferred Stock will be convertible into 0.05357 shares of Common Stock and each share of Series B Convertible Preferred Stock will be convertible into 0.03571 share of Common Stock, subject to certain anti-dilution protections, at the option of the holder. Each share of Preferred Stock will automatically convert upon (i) the closing of the sale of shares of Common Stock in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act, resulting in at least \$45.0 million of gross proceeds to the Company (a "qualified initial public offering"), or (ii) the occurrence of an event, specified by a vote or written consent of the holders of a majority of the then outstanding shares of Preferred Stock. As of June 30, 2015, the Preferred Stock is convertible into 3,980,422 shares of Common Stock.

The Preferred Stock is subject to redemption under certain "deemed liquidation" events, as defined, and as such, the Preferred Stock is considered contingently redeemable for accounting purposes. Accordingly, the Preferred Stock has been recorded within temporary equity in the financial statements. The Company has not adjusted the Preferred Stock to its redemption amount at each reporting period, as the redemption of such Preferred Stock is not deemed probable of occurrence during the periods presented. The redemption of the Preferred Stock is not considered probable as the redemption is contingent on the occurrence of such "deemed liquidation" events, which include (i) the acquisition of the Company by another entity by means of any transaction or a series of related transactions, unless the existing stockholders of the Company continue to hold at least 50% of the voting power of the surviving or acquiring entity after such transaction; and (ii) a sale of all or substantially all of the assets of the Company. The Company has concluded that none of these events are probable during the periods presented.

Since the issuance of Series B Convertible Preferred Stock, all series of Preferred Stock are entitled to a non-cumulative annual dividend of 8.0%. Dividends are paid when, as, and if declared by the board of directors. In the event of any liquidation, dissolution or winding up of the Company prior

**CERECOR INC.**

**Notes to Unaudited Financial Statements (Continued)**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015**

**8. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)**

to the conversion, the holders of the Preferred Stock will be entitled to a liquidation preference in pari passu before any liquidation preference payments are made to the Common shareholders. The liquidation preference payment is equal to the greater of (i) original issuance plus any declared but unpaid dividends, or (ii) the amount that a Preferred holder would have been entitled to receive if they had converted to common immediately prior to liquidation.

***Series B Convertible Preferred Stock Transaction***

On July 11, 2014, the Company completed an initial closing of an equity offering for shares of its Series B Convertible Preferred Stock and on August 19, 2014 completed a second closing. Pursuant to the terms of the agreement, the Company issued an aggregate of 50,017,786 shares of Series B Convertible Preferred Stock at an original issuance price of \$0.2999 per share for gross proceeds of \$15,000,000.

In addition, and pursuant to the terms of, several convertible promissory notes issued from April through June 2014, the Company issued 5,597,618 shares of Series B Convertible Preferred Stock upon the conversion of the outstanding principal and interest due under the convertible promissory notes in the aggregate amount of \$1,259,016. The conversion price for the convertible promissory notes was equal to \$0.22492, or 75% of the original issuance price of the Series B Convertible Preferred Stock. The demand notes issued in July 2014, with an aggregate principal balance of \$996,666, was converted into 3,333,331 shares of Series B Convertible Preferred Stock at a conversion price of \$0.2999 per share. See Note 7 for additional information regarding the terms and provisions of the convertible promissory notes and demand notes.

The second closing of the Series B Convertible Preferred Stock equity offering was with the term loan lender. Pursuant to the same terms and conditions of the initial offering, the Company issued 3,334,445 shares of Series B Convertible Preferred Stock to the term loan lender at an original issuance price of \$0.2999 per share, for gross proceeds of \$1,000,000, which is included in the \$15,000,000 described above.

The right of the investors (the "Investor Rights Obligation") to purchase Series B Convertible Preferred Stock represented a freestanding financial instrument and was indexed to an obligation of the Company to repurchase its Series B Convertible Preferred Stock by transferring assets. As such, the Company accounted for the Investor Rights Obligation as a liability in accordance with FASB ASC 480. The Company adjusted the carrying value of the liability to its estimated fair value at each reporting date (see Note 3).

**CERECOR INC.****Notes to Unaudited Financial Statements (Continued)****As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015****8. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)*****Common Stock Warrants***

At June 30, 2015, the following Common Stock warrants were outstanding (all of which are accounted for as equity instruments):

<u>Number of shares underlying warrants</u>	<u>Exercise price per share</u>	<u>Expiration Date</u>
109,976	\$ 28.00	February 2017
29,260	\$ 14.00	February 2017
90,529	\$ 28.00	March 2017
29,557	\$ 14.00	March 2017
130,233	\$ 28.00	April 2017
14,284	\$ 28.00	July 2017
80,966	\$ 28.00	August 2018
3,571	\$ 28.00	December 2018
59,542	\$ 8.40	April 2019*
23,816	\$ 8.40	May 2019*
65,497	\$ 8.40	June 2019*
17,863	\$ 8.40	July 2019*
2,380	\$ 8.68	May 2022
<u>657,474</u>		

\* each of these warrants will expire upon the closing of an initial public offering, if sooner, in accordance with their terms.

On June 12, 2015, the Company and Maxim Partners LLC ("Maxim") entered into an agreement to terminate a warrant to purchase 24,306 shares of Common Stock at an exercise price of \$21.00 per share. The cancellation of the warrant was effective immediately without any consideration due to Maxim.

***Series B Convertible Preferred Stock Warrants***

In August 2014, a warrant to purchase 625,208 shares of Series B Convertible Preferred Stock, at an exercise price equal to \$0.2999 per share, was issued to the term loan lender in conjunction with the loan of \$7.5 million (see Note 7). The fair value was calculated at \$115,056 using a Black-Scholes pricing model using a fair market value of \$0.25 per share for its Series B Convertible Preferred Stock.

**9. STOCK-BASED COMPENSATION*****2011 Stock Incentive Plan***

On April 28, 2011, the board of directors adopted the 2011 Stock Incentive Plan (the "Plan") reserving and authorizing up to 178,571 shares of Common Stock for stock-based compensation awards to attract, retain and reward eligible employees, consultants, and non-employee directors. The options have a contractual term of ten years. Generally, the options vest annually over three or four years, as



**CERECOR INC.****Notes to Unaudited Financial Statements (Continued)**

**As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
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**9. STOCK-BASED COMPENSATION (Continued)**

determined by the board of directors, upon each option grant, although certain option grants in 2014 were fully vested on the grant date. On January 10, 2012, the board of directors and stockholders of the Company approved an amendment to the Plan authorizing an increase in the aggregate number of shares reserved for issuance under the Plan from 178,571 to 285,714 shares of Common Stock. On May 6, 2013, the board of directors approved an amendment to the Plan authorizing an increase in the aggregate number of shares reserved for issuance under the Plan from 285,714 to 704,428 shares of Common Stock. As of June 30, 2015, there were 254,236 shares remaining under the Plan available for future issuance.

On May 8, 2012, the board of directors approved three grants of non-qualified stock options outside of the Plan aggregating 167,857 to the President and Chief Executive Officer and two non-employee directors of the Company at \$8.68 per share, one-third vesting on three consecutive annual anniversaries.

The estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized was as follows:

	Six Months Ended June 30, 2014	Six Months Ended June 30, 2015
Research and development	\$ 78,194	\$ 43,367
General and administrative	403,109	248,846
<b>Total stock-based compensation</b>	<b>\$ 481,303</b>	<b>\$ 292,213</b>

A summary of option activity is as follows:

	Options Outstanding			Weighted Average Remaining Contractual Term (in years)
	Number of Shares	Weighted-Average Exercise Price	Fair Value Of Options Granted	
Balance, December 31, 2014	552,726	\$ 9.17		8.17
Granted	72,856	\$ 6.22	\$ 211,262	
Forfeitures	(114,698)	\$ 8.59		
Balance, June 30, 2015	510,884	\$ 8.88		7.39
Vested or expected to vest at June 30, 2015	510,884	\$ 8.88		7.39
Exercisable at June 30, 2015	439,607	\$ 9.26		7.54

**CERECOR INC.****Notes to Unaudited Financial Statements (Continued)****As of December 31, 2014 and June 30, 2015 and for the Six Months Ended  
June 30, 2014 and 2015****9. STOCK-BASED COMPENSATION (Continued)**

As of June 30, 2015, there was \$0.2 million of total unrecognized compensation expense, related to unvested options granted under the Plan, unvested options granted outside of the Plan, and restricted stock to be recognized as follows:

<u>Year ending December 31,</u>	
*2015	\$ 48,108
2016	57,419
2017	45,932
2018	42,495
2019	14,113
Total	<u>\$ 208,067</u>

\* Six months remaining in 2015

**10. SUBSEQUENT EVENTS*****Reverse Stock Split***

On June 26, 2015, the Company's board of directors approved a one-for-28 reverse stock split of the Company's Common Stock. As a result of the reverse stock split, (i) each 28 shares of then-outstanding Common Stock was reduced to one share of Common Stock; (ii) the number of shares of Common Stock into which each then-outstanding share of our Series A, A-1 and B Convertible Preferred Stock and our then-outstanding warrants or options to purchase shares of Common Stock are convertible or exercisable into, was proportionately reduced; and (iii) the exercise price of each then-outstanding warrant or option to purchase shares of Common Stock was proportionately increased. Fractional shares resulting from the reverse stock split have been rounded down to the next whole share and in lieu of any fractional shares the Company will pay a cash amount to the holder of such fractional share equal to the fair market value of such fractional share as determined by the Company's board of directors. On September 1, 2015, the Company filed an amendment to its amended and restated certificate of incorporation effecting such reverse stock split. All share and per share amounts of common stock in the accompanying financial statements have been restated for all periods to give retroactive effect to the reverse stock split. The shares of common stock retained a par value of \$0.001 per share. Accordingly, the stockholders' deficit reflects the reverse stock split by reclassifying from Common Stock to Additional Paid-In Capital in an amount equal to the par value of the decreased shares resulting from the reverse stock split.

***Amended Certificate of Incorporation***

On September 1, 2015, the Company filed an amendment to its amended and restated certificate of incorporation to give effect to the reverse stock split and revised the definition of a Qualified Public Offering so that the Preferred Stock will automatically convert upon the closing of the sale of shares of Common Stock to the public in an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended.



**4,230,769 Shares**

**Common Stock**

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**PROSPECTUS**

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, 2015

**Maxim Group LLC**

**Laidlaw & Company (UK) Ltd.**

Through and including \_\_\_\_\_, 2015 (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 dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by the registrant. All amounts are estimates except the Securities and Exchange Commission registration fee, Financial Industry Regulatory Authority, Inc. filing fee and the listing fee for the NASDAQ Capital Market.

	<u>Amount</u>
Securities and Exchange Commission registration fee	\$ 3,675
Financial Industry Regulatory Authority, Inc. filing fee	5,244
NASDAQ Capital Market initial listing fee	50,000
Accountants' fees and expenses	850,000
Legal fees and expenses	900,000
Transfer Agent's fees and expenses	5,000
Printing and engraving expenses	250,000
Miscellaneous	150,000
Total Expenses	<u>\$ 2,213,919</u>

The expense amounts set forth above are treated as deferred offering costs and will be deferred until this offering is completed. The amount excludes \$1.1 million of expenses that have been incurred and not deferred, but rather expensed, in 2014 because we had determined that this offering was no longer probable of being consummated at such time.

**Item 14. Indemnification of Directors and Officers.**

We are incorporated under the laws of the State of Delaware. Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty to the corporation or its stockholders, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock purchase or redemption in violation of Delaware corporate law or derived an improper personal benefit. Our amended and restated certificate of incorporation that will be effective upon the closing of this offering provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with

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respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnify for such expenses which the Court of Chancery or such other court shall deem proper.

Our amended and restated certificate of incorporation that will be effective upon the closing of the offering provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Our amended and restated certificate of incorporation that will be effective upon the closing of the offering also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If we do not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

In addition, we expect to enter into indemnification agreements with our current directors and officers containing provisions which are in some respects broader than the specific indemnification provisions contained in the Delaware general Corporation Law. The indemnification agreements require us, among other things, to indemnify our directors against certain liabilities that may arise by reason of their status or service as directors and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

The underwriting agreement we will enter into in connection with the offering of common stock being registered hereby provides that the underwriters will indemnify, under certain conditions, our directors and officers (as well as certain other persons) against certain liabilities arising in connection with such offering.

**Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding shares of common stock and preferred stock issued, and options granted, by us within the past three years that were not registered under the Securities Act of 1933, as amended (the "Securities Act"). Also included is the consideration, if any, received by us for such shares and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

**(a) Issuances of Securities**

In September 2014, we issued a warrant to purchase 2,380 shares of our common stock to a member of our board of directors in consideration for his past services to the Company.

In August 2014, we entered into a \$7.5 million secured term loan facility and in connection with such loan we issued the lender a warrant to purchase 625,208 shares of Series B preferred stock at an exercise price of \$0.2999 per share. Upon the closing of this offering, in accordance with their terms, the warrants will automatically become exercisable for 22,328 shares of common stock at an exercise price of \$8.40 per share of common stock.

In August 2014, we issued and sold to an investor at a purchase price of \$0.2999 per share an aggregate of 3,334,445 shares of our Series B convertible preferred stock for an aggregate purchase price of \$1.0 million.

In July 2014, we issued and sold to investors at a purchase price of \$0.2999 per share an aggregate of 55,614,290 shares of our Series B convertible preferred stock for an aggregate consideration of \$14,000,334 in cash and \$2,258,682 in aggregate principal and interest due under convertible promissory notes held by existing investors.

In July 2014, we issued convertible demand promissory notes to investors in an aggregate principal amount of \$1.0 million. In July 2014, the convertible promissory notes converted into shares of Series B convertible preferred stock in accordance with the terms of such notes.

In July 2014, we issued a warrant to purchase 17,863 shares of our common stock to a consulting firm in partial consideration for advisory services.

From April 2014 through June 2014, we issued convertible promissory notes, to investors in an aggregate principal amount of \$1,250,000. In connection with the issuance of these notes, we issued warrants to purchase 148,854 shares our common stock. In July 2014, the convertible promissory notes converted into shares of Series B convertible preferred stock in accordance with the terms of such notes.

In December 2013, we issued a warrant to purchase 3,571 shares of our common stock to a consulting firm in partial consideration for the consulting services in connection with identifying commercial opportunities.

In August 2013, we issued and sold to investors at a purchase price of \$0.75 per unit an aggregate of 9,074,511 shares of our Series A-1 convertible preferred stock and warrants to purchase 80,966 shares of our common stock for an aggregate purchase price of \$6.8 million.

In August 2013, in connection with the sale of the Series A-1 convertible preferred stock, we issued a warrant to purchase 24,306 shares of our common stock to the placement agent in such offering.

In May 2012, we issued and sold to investors at a purchase price of \$0.75 per unit an aggregate of 1,600,000 shares of our Series A convertible preferred stock and warrants to purchase 14,285 shares of our common stock for an aggregate purchase price of \$1.2 million.

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In April 2012, we issued and sold to investors at a purchase price of \$0.75 per unit an aggregate of 464,000 shares of our Series A convertible preferred stock and warrants to purchase 4,142 shares of our common stock for an aggregate purchase price of \$348,000.

In April 2012, in connection with the sale of the Series A convertible preferred stock, we issued a warrant to purchase 126,091 shares of our common stock to the placement agent in such offerings.

In March 2012, we issued and sold to investors at a purchase price of \$0.75 per unit an aggregate of 12,854,643 shares of our Series A convertible preferred stock and warrants to purchase 114,773 shares of our common stock for an aggregate purchase price of \$9.6 million. We also issued 4,077,475 shares of our Series A convertible preferred stock and a warrant to purchase 36,406 shares of our common stock upon the conversion of the convertible demand promissory note issued in April 2011.

In February 2012, we issued and sold to investors at a purchase price of \$0.75 per unit an aggregate of 12,120,273 shares of our Series A convertible preferred stock and warrants to purchase 108,216 shares of our common stock for an aggregate purchase price of \$9.1 million.

No underwriters were involved in the foregoing sales of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of shares of our preferred stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

**(b) Stock Option and Restricted Stock Grants**

Since inception, we have (i) issued 107,142 shares of restricted common stock, at a purchase price of \$0.001 per share, to an executive officer pursuant to the 2011 Stock Incentive Plan, (ii) granted stock options to purchase an aggregate of 465,974 shares of our common stock, with exercise prices ranging from \$0.28 to \$16.80 per share, to employees, directors and consultants pursuant to the 2011 Stock Incentive Plan and (iii) granted stock options to purchase an aggregate of 167,857 shares of our common stock, with an exercise price of \$8.68 per share, to employees, directors and consultants outside of the 2011 Stock Incentive Plan. Of these options, none have been exercised.

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities described in sections (a) and (b) of Item 15 are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

**Item 16. Exhibits and Financial Statement Schedules.**

- (a) The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

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(b) No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.



**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Baltimore, State of Maryland, on this 22<sup>nd</sup> day of September, 2015.

CERECOR INC.

By:           /s/ BLAKE M. PATERSON, M.D.

\_\_\_\_\_  
Blake M. Paterson, M.D.  
*President and Chief Executive Officer*

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>          /s/ BLAKE M. PATERSON, M.D.</u> Blake M. Paterson, M.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	September 22, 2015
<u>          /s/ MARIAM E. MORRIS</u> Mariam E. Morris	Chief Financial Officer (Principal Financial and Accounting Officer)	September 22, 2015
*		
<u>          Eugene A. Bauer, M.D.</u>	Director	September 22, 2015
*		
<u>          Isaac Blech</u>	Director	September 22, 2015
*		
<u>          Phil Gutry</u>	Director	September 22, 2015
*		
<u>          Uli Hacksell, Ph.D.</u>	Director	September 22, 2015
*		
<u>          Magnus Persson, M.D., Ph.D.</u>	Director	September 22, 2015
*		
<u>          Behshad Sheldon</u>	Director	September 22, 2015

\* Blake M. Paterson, by signing his name hereto, does hereby sign this document on behalf of each of the above-named directors of the registrant pursuant to powers of attorney duly executed by such persons.

By:           /s/ BLAKE M. PATERSON, M.D.  
Blake M. Paterson, M.D.  
*Attorney-in-fact*

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
1.1	Form of Underwriting Agreement
3.1 <sup>†</sup>	Certificate of Incorporation of Cerecor Inc., as currently in effect
3.2 <sup>†</sup>	Form of Amended and Restated Certificate of Incorporation of Cerecor Inc. (to become effective upon the closing of this offering)
3.3 <sup>†</sup>	Bylaws of Cerecor Inc., as currently in effect
3.4 <sup>†</sup>	Form of Amended and Restated Bylaws of Cerecor Inc. (to become effective upon the closing of this offering)
4.1 <sup>†</sup>	Second Amended and Restated Investors' Rights Agreement, dated as of July 11, 2014
4.2 <sup>†</sup>	Form of Warrant to Purchase Shares of Common Stock issued in connection with the sale of Series A Convertible Preferred Stock
4.3 <sup>†</sup>	Form of Warrant to Purchase Shares of Common Stock issued in connection with the sale of Series A-1 Convertible Preferred Stock, as amended by the Amendment to Common Stock Warrants, dated as of July 11, 2014
4.4 <sup>†</sup>	Common Stock Warrant, dated as of April 4, 2012, issued to Maxim Partners LLC
4.5 <sup>†</sup>	Form of Warrant to Purchase Shares of Common Stock, issued to CIFCO International Group and its affiliate.
4.6 <sup>†</sup>	Form of Warrant to Purchase Shares of Common Stock issued in connection with the issuance of convertible promissory notes from April 2014 through June 2014
4.7 <sup>†</sup>	Warrant Agreement, dated as of August 19, 2014, issued to Hercules Technology Growth Capital, Inc.
4.8	Form of Underwriters' Warrants to Purchase Common Stock of Cerecor (included in Exhibit 1.1, Annex IV)
5.1 <sup>†</sup>	Opinion of Morgan, Lewis & Bockius LLP
10.1 <sup>#†</sup>	Exclusive Patent and Know-How License Agreement, effective as of March 19, 2013, by and between Essex Chemie AG and Cerecor Inc.
10.2 <sup>#†</sup>	Exclusive Patent and Know-How License Agreement, effective as of March 19, 2013, by and between Essex Chemie AG and Cerecor Inc.
10.3 <sup>#†</sup>	Exclusive Patent and Know-How License Agreement, effective as of February 18, 2015, by and between Eli Lilly and Company and Cerecor Inc.
10.4 <sup>+†</sup>	Cerecor Inc. 2011 Stock Incentive Plan, as amended, including forms of Incentive Stock Option Agreements and Nonqualified Stock Option Agreements thereunder
10.5 <sup>+†</sup>	Cerecor Inc. 2015 Omnibus Incentive Plan, including form of Nonqualified Stock Option Agreements thereunder
10.6 <sup>+†</sup>	Offer Letter Agreement by and between Cerecor Inc. and Blake M. Paterson, dated as of April 28, 2011
10.7 <sup>+†</sup>	Offer Letter Agreement by and between Cerecor Inc. and John Kaiser, dated as of September 12, 2012

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.8 <sup>+†</sup>	Offer Letter Agreement by and between Cerecor Inc. and James Vornov, dated as of September 18, 2012
10.9 <sup>+†</sup>	Offer Letter Agreement by and between Cerecor Inc. and Ronald Marcus, dated as of May 5, 2015
10.10 <sup>+†</sup>	Offer Letter Agreement by and between Cerecor Inc. and Uli Hacksell, dated as of May 20, 2015
10.11 <sup>+†</sup>	Offer Letter Agreement by and between Cerecor Inc. and Mariam Morris, effective as of August 24, 2015
10.12 <sup>+†</sup>	Form of Director Indemnification Agreement
10.13 <sup>†</sup>	List of current directors with a Director Indemnification Agreement in the form provided as Exhibit 10.12
10.14 <sup>†</sup>	Lease Agreement by and between Cerecor Inc. and PDL Pratt Associates, LLC, dated as of August 8, 2013
10.15 <sup>†</sup>	Loan and Security Agreement, dated as of August 19, 2014, by and between Cerecor Inc. and Hercules Technology Growth Capital, Inc.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
23.2 <sup>†</sup>	Consent of Morgan, Lewis and Bockius LLP (included in Exhibit 5.1)
24.1 <sup>†</sup>	Power of Attorney (included in the signature page to this registration statement)

+ Management contract or compensatory agreement.

# Confidential treatment requested under 17 C.F.R. §§ 200.80(b)(4) and 230.406. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission.

† Previously filed.



## CERECOR INC.

## UNDERWRITING AGREEMENT

, 2015

MAXIM GROUP LLC  
405 Lexington Avenue  
New York, NY 10174

*As Representative of the Underwriters  
named on Schedule I hereto*

Ladies and Gentlemen:

The undersigned, Cerecor Inc., a Delaware corporation (the “**Company**”), hereby confirms its agreement (this “**Agreement**”) with the several underwriters named in Schedule I hereto (the “**Underwriters**” and each an “**Underwriter**”), for whom Maxim Group LLC is acting as representative (in such capacity, the “**Representative**”), to issue and sell to the Underwriters an aggregate of [ ] shares (the “**Firm Shares**”) of the Company’s common stock, par value \$0.001 per share (the “**Common Stock**”). In addition, the Company shall grant to the Underwriters an option (the “**Over-Allotment Option**”) to purchase up to an additional [ ] shares (the “**Option Shares**”) of Common Stock from the Company for the purpose of covering over-allotments in connection with the sale of the Firm Shares. The Firm Shares and the Option Shares are hereinafter referred to collectively as the “**Securities**.” The offering and sale of the Securities contemplated by this Agreement is referred to herein as the “**Offering**.”

The Company has prepared and filed in conformity with the requirements of the Securities Act of 1933, as amended (the “**Securities Act**”), and the published rules and regulations thereunder (the “**Rules and Regulations**”) adopted by the Securities and Exchange Commission (the “**Commission**”) a Registration Statement (as hereinafter defined) on Form S-1 (No.333-204905), including a preliminary prospectus relating to the Securities, and such amendments thereof as may have been required through the date of this Agreement. Copies of such Registration Statement (including all amendments thereof) and of the related Preliminary Prospectus (as hereinafter defined) have heretofore been made available by the Company to you. The term “**Preliminary Prospectus**” means any preliminary prospectus subject to completion included at any time as a part of the Registration Statement or filed with the Commission by the Company pursuant to Rule 424 of the Rules. The term “**Registration Statement**” as used in this Agreement means the initial registration statement (including all exhibits and financial schedules and all other information (if any) deemed to be a part of the Registration Statement), as amended and on the date it becomes effective (the “**Effective Date**”), including the information (if any) contained in the form of final prospectus filed with the Commission pursuant to Rule 424(b) of the Rules and, deemed to be part thereof at the time of effectiveness pursuant to Rule 430A of the Rules. If the Company has filed or is required to file pursuant to the terms hereof an abbreviated registration statement to register additional Shares pursuant to Rule 462(b) under the Rules (the “**462(b) Registration Statement**”), then any reference herein to the Registration Statement, unless otherwise specified, shall also be deemed to include such 462(b) Registration

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Statement. The term “**Prospectus**” as used in this Agreement means the prospectus in the form in which it is filed with the Commission pursuant to Rule 424(b) of the Rules, or, if the prospectus is not to be filed with the Commission pursuant to Rule 424(b), the prospectus in the form included as part of the Registration Statement at the time the Registration Statement became effective.

The Company understands that the Underwriters propose to make a public offering of the Firm Shares, as soon after the date of this Agreement as the Representative deems advisable. As the Representative, you have advised the Company that you are authorized to enter into this Agreement on behalf of the several Underwriters. The Company hereby confirms that the Underwriters and dealers have been authorized to distribute or cause to be distributed each Preliminary Prospectus, and each Issuer Free Writing Prospectus (as hereinafter defined) and are authorized to distribute the Prospectus (as from time to time amended or supplemented if the Company furnishes amendments or supplements thereto to the Underwriters).

Any reference herein to the Registration Statement, any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include the exhibits incorporated by reference therein pursuant to the Rules and Regulations on or before the Effective Date (as defined below) of the Registration Statement, the date of such Preliminary Prospectus or the date of the Prospectus, as the case may be. Any reference herein to the terms “amend”, “amendment” or “supplement” with respect to the Registration Statement, any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include: (i) the filing of any document under the Securities Exchange Act of 1934, as amended, and together with the Rules and Regulations promulgated thereunder (the “**Exchange Act**”) after the Effective Date, the date of such Preliminary Prospectus or the date of the Prospectus, as the case may be, which is incorporated therein by reference, and (ii) any such document so filed. All references in this Agreement to the Registration Statement, the Rule 462(b) Registration Statement, a Preliminary Prospectus and the Prospectus, or any amendments or supplements to any of the foregoing, shall be deemed to include any copy thereof filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System (“**EDGAR**”). The Prospectus delivered to the Underwriters for use in connection with the Offering was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T promulgated by the Commission.

1. Securities; Over-Allotment Option.

(a) Purchase of Firm Shares. On the basis of the representations and warranties herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell, severally and not jointly, to the several Underwriters, the Firm Shares at a purchase price (net of discounts and commissions) of \$[ ] for each Firm Share, which represents a 7.5% discount to the public offering price per Firm Share. The Underwriters, severally and not jointly, agree to purchase from the Company the number of Firm Shares set forth opposite their respective names on Schedule I attached hereto and made a part hereof, plus any additional number of Firm Shares which such Underwriter may become obligated to purchase pursuant to the provisions of Section 9 hereof, subject to such adjustments among the Underwriters as the Representative in its sole discretion shall make to eliminate any sales or purchases of fractional

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Firm Shares provided that the total number of Firm Shares shall not be reduced by such adjustment.

(b) Payment and Delivery. Delivery and payment for the Firm Shares shall be made at 10:00 a.m., New York time, on the third Business Day following the Effective Date of the Registration Statement (or the fourth Business Day following the Effective Date, if the Registration Statement is declared effective after 4:30 p.m. New York time) or at such earlier time as shall be agreed upon by the Representative and the Company at the offices of the Representative or at such other place as shall be agreed upon by the Representative and the Company. The hour and date of delivery and payment for the Firm Shares is called the “**Closing Date.**” The closing of the payment of the purchase price for, and delivery of certificates representing, the Firm Shares is referred to herein as the “**Closing.**” Payment for the Firm Shares shall be made on the Closing Date by wire transfer in Federal (same day) funds upon delivery to you of certificates (in form and substance satisfactory to the Underwriters) representing the Firm Shares (or through the full fast transfer facilities of the Depository Trust Company (the “**DTC**”)) for the account of the Underwriters. It is understood that each Underwriter has authorized the Representative, for its account, to accept delivery of, receipt for, and make payment of the purchase price for, the Firm Shares which it has agreed to purchase. The Firm Shares shall be registered in such name or names and in such authorized denominations as the Representative may request in writing at least two Business Days prior to the Closing Date. The Company will permit the Representative to examine and package the Firm Shares at least one full Business Day prior to the Closing Date. The Company shall not be obligated to sell or deliver the Firm Shares except upon tender of payment by the Representative for all the Firm Shares.

(c) Over-allotment Option. For the purposes of covering any over-allotments in connection with the distribution and sale of the Firm Shares, the Representative on behalf of the Underwriters is hereby granted the Over-Allotment Option to purchase up to [ ] Option Shares. The purchase price to be paid for the Option Shares subject to the Over-allotment Option will be equal to \$[ ] per Option Share (net of discounts and commissions).

(d) Exercise of Option. The Over-Allotment Option granted pursuant to Section 1(c) hereof may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Shares within 45 days after the Closing Date. The Underwriters will not be under any obligation to purchase any of such Option Shares prior to the exercise of the Over-allotment Option. The Over-Allotment Option granted hereby may be exercised by the giving of written notice to the Company from the Representative, setting forth the number of Option Shares to be purchased and the date and time for delivery of and payment for such Option Shares, which will not be later than five Business Days, or earlier than two Business Days, after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of the Representative or at such other place as shall be agreed upon by the Company and the Representative. If such delivery and payment for all of the Option Shares does not occur on the Closing Date, the date and time of the closing for such Option Shares will be as set forth in the notice (hereinafter the “**Option Closing Date**”). Upon exercise of the Over-Allotment Option, the Company will become obligated to convey to the Underwriters, and, subject to the terms and conditions set forth herein, the Underwriters will become obligated to purchase, the number of Option Shares specified in such notice. If any Option Shares are to be purchased, each Underwriter agrees, severally and not jointly, to

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purchase the number of Option Shares (subject to such adjustments to eliminate fractional shares as the Representative may determine provided that the total number of Option Shares shall not be reduced by such adjustment) that bears the same proportion to the number of Firm Shares to be purchased as set forth on Schedule I opposite the name of such Underwriter.

(e) Payment and Delivery of Option Shares. Payment for Option Shares shall be made on the Option Closing Date by wire transfer in Federal (same day) funds by deposit of the price for the Option Shares being purchased to the Company upon delivery to the Underwriters of certificates (in form and substance satisfactory to the Underwriters) representing such Option Shares (or through the full fast transfer facilities of DTC) for the account of the Underwriters. It is understood that each Underwriter has authorized the Representative, for its account, to accept delivery of, receipt for, and make payment of the purchase price for, the Option Shares which it has agreed to purchase. The certificates representing the Option Shares to be delivered will be in such denominations and registered in such names as the Representative shall request not less than two Business Days prior to the Option Closing Date. The Company will permit the Representative to examine and package the Option Shares at least one full Business Day prior to the Closing Date. The Company shall not be obligated to sell or deliver the Option Shares except upon tender of payment by the Representative for all the Option Shares being purchased on the Closing Date.

(f) Representative’s Warrants. The Company hereby agrees to issue to the Representative (and/or its designees) on the Closing Date warrants to purchase a number of shares of Common Stock equal to one percent (1%) of the Firm Shares sold at the Closing (the “**Representative’s Warrants**”). The Representative’s Warrants shall be immediately exercisable, in whole or in part, commencing on the Effective Date and expiring on the five-year anniversary of the Effective Date at an initial exercise price of \$[ ] per share of

Common Stock, which is equal to one hundred fifteen percent (115%) of the initial public offering price of a Firm Share. The Representative's Warrants and the Common Stock issuable upon exercise of the Representative's Warrants are hereinafter referred to collectively as the "**Representative's Securities**." The Representative's Securities shall not sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities for a period of 180 days following the Effective Date.

2. Representations and Warranties of the Company. The Company represents and warrants to each of the Underwriters (except with respect to Section 2(e)) that, as of the date hereof and as of the Closing Date:

(a) On the Effective Date, the Registration Statement complied, in all material respects, with the applicable provisions of the Securities Act, the Exchange Act and the Rules and Regulations. On the date of the Prospectus, the date any supplement or amendment to the Prospectus is filed with the Commission, and on the Closing Date and the Option Closing Date, if any, the Registration Statement and the Prospectus complied or will comply, in all material respects, with the applicable provisions of the Securities Act, the Exchange Act and the Rules and Regulations. Neither the Registration Statement, nor any amendment thereto, on the Effective Date, as of the Applicable Time or on the Closing Date or the Option Closing Date, if any, contained or will contain any untrue statement of a material fact or omitted or will omit to

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state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. Neither the Prospectus, nor any amendment thereof or supplement thereto, as of its issued date, at the time of filing with the Commission pursuant to Rule 424(b), at the Closing Date and the Option Closing Date, if any, contained or will contain an untrue statement of a material fact or omitted or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. When any Preliminary Prospectus was submitted to or filed with the Commission (whether as part of the Registration Statement or any amendment thereto or pursuant to Rule 424(a) under the Securities Act) and when any amendment thereof or supplement thereto was first submitted to or filed with the Commission, such Preliminary Prospectus and any amendments thereof and supplements thereto complied in all material respects with the applicable provisions of the Securities Act, the Exchange Act and the Rules and Regulations and did not contain an untrue statement of a material fact and did not omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. No representation and warranty is made in this subsection (a), however, with respect to any information contained in or omitted from the Registration Statement or the Prospectus or any related Preliminary Prospectus or any amendment thereof or supplement thereto in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of any Underwriter through the Representative specifically for use therein. The parties acknowledge and agree that such information provided by or on behalf of any Underwriter consists solely of: the statements set forth in the "Underwriting" section of the Prospectus only insofar as such statements relate to the names and corresponding share amounts set forth in the table of Underwriters, the amount of selling concession and re-allowance or to over-allotment and related activities that may be undertaken by the Underwriters, the paragraph relating to stabilization by the Underwriters and such other information contained in the "Underwriting" section of the Prospectus relating to the Underwriters that was provided in writing by the Underwriters (the "**Underwriters' Information**").

(b) The Issuer-Represented Free Writing Prospectus(es) (as defined below) issued at or prior to the Applicable Time (as defined below) and the Statutory Prospectus (as defined below), all considered together (collectively, the "**General Disclosure Package**"), did not include as of the Applicable Time any untrue statement of a material fact or omit as of the Applicable Time to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from any Statutory Prospectus included in the Registration Statement, the General Disclosure Package or any Issuer-Represented Free Writing Prospectus in conformity with the Underwriters' Information.

(c) Each Issuer-Represented Free Writing Prospectus, as of its issue date and at all subsequent times until the Closing Date or until any earlier date that the Company notified or notifies the Representative as described in the next sentence, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the then-current Registration Statement, Statutory Prospectus or Prospectus. If at any time following issuance of an Issuer-Represented Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer-Represented Free Writing Prospectus conflicted or would conflict with the information contained in the then-current Registration

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Statement, Statutory Prospectus or Prospectus relating to the Securities or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company has notified or will notify promptly the Representative so that any use of such Issuer-Represented Free Writing Prospectus may cease until it is promptly amended or supplemented by the Company, at its own expense, to eliminate or correct such conflict, untrue statement or omission. The foregoing two sentences do not apply to statements in or omissions from any Issuer-Represented Free Writing Prospectus based upon and in conformity with the Underwriters' Information.

(d) Neither the Company, nor to the Company's knowledge any of its officers, directors or Affiliates (as defined in the Securities Act), has distributed and will not distribute any prospectus or other offering material in connection with the offering and sale of the Securities other than the General Disclosure Package, any Issuer-Represented Free Writing Prospectus or the Prospectus or other materials permitted by the Securities Act to be distributed by the Company. Unless the Company obtains the prior written consent of the Representative, the Company has not made and will not make any offer relating to the Securities that would constitute an "issuer free

writing prospectus,” as defined in Rule 433 under the Securities Act, or that would otherwise constitute a “free writing prospectus,” as defined in Rule 405 under the Securities Act, required to be filed with the Commission; provided that the prior written consent of the Representative shall be deemed to have been given in respect of any free writing prospectus referenced on Schedule II attached hereto. The Company has complied and will comply with the requirements of Rules 164 and 433 under the Securities Act applicable to any Issuer-Represented Free Writing Prospectus as of its issue date and at all subsequent times through the Closing Date, including timely filing with the Commission where required, legending and record keeping. To the extent an electronic road show is used, the Company has satisfied and will satisfy the conditions in Rule 433 under the Securities Act to avoid a requirement to file with the Commission any electronic road show.

(e) The Representative covenants and agrees that, unless it obtains the prior written consent of the Company, it will not make any offer relating to the Securities that would constitute an Issuer-Represented Free Writing Prospectus or that would otherwise (without taking into account any approval, authorization, use or reference thereto by the Company) constitute a “free writing prospectus” required to be filed by the Company with the Commission or retained by the Company under Rule 433 of the Securities Act; provided that the prior written consent of the Company hereto shall be deemed to have been given in respect of any Issuer-Represented Free Writing Prospectuses referenced on Schedule II attached hereto.

(f) As used in this Agreement, the terms set forth below shall have the following meanings:

(i) “**Applicable Time**” means , 2015 (Eastern time) on the date of this Agreement.

(ii) “**Statutory Prospectus**” as of any time means the prospectus that is included in the Registration Statement immediately prior to that time. For purposes of this definition, information contained in a form of prospectus that is deemed retroactively to be a part

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of the Registration Statement pursuant to Rule 430A or 430B shall be considered to be included in the Statutory Prospectus as of the actual time that form of prospectus is filed with the Commission pursuant to Rule 424(b) under the Securities Act.

(iii) “**Issuer-Represented Free Writing Prospectus**” means any “issuer free writing prospectus,” as defined in Rule 433 under the Securities Act, relating to the Securities that (A) is required to be filed with the Commission by the Company, or (B) is exempt from filing pursuant to Rule 433(d)(5)(i) under the Securities Act because it contains a description of the Securities or of the Offering that does not reflect the final terms or pursuant to Rule 433(d)(8)(ii) because it is a “bona fide electronic road show,” as defined in Rule 433 under the Securities Act, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g) under the Securities Act, as evidenced by its being specified in Schedule II to this Agreement..

(g) Ernst & Young LLP (the “**Auditor**”), whose reports relating to the Company are included in the Registration Statement, the General Disclosure Package and the Prospectus, to the Company’s knowledge, is an independent registered public accounting firm as required by the Securities Act, the Exchange Act and the Rules and Regulations and the Public Company Accounting Oversight Board (the “**PCAOB**”). To the Company’s knowledge, the Auditor is not in violation of the auditor independence requirements of the Sarbanes-Oxley Act of 2002 (“**Sarbanes-Oxley**”). The Auditor has not, during the periods covered by the financial statements included in the Registration Statement, the General Disclosure Package and the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

(h) Subsequent to the respective dates as of which information is presented in the Registration Statement, the General Disclosure Package and the Prospectus, and except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus: (i) the Company has not declared, paid or made any dividends or other distributions of any kind on or in respect of its capital stock, and (ii) there has been no material adverse change (or, to the Company’s knowledge, any development which could reasonably be expected to result in a material adverse change in the future), whether or not arising from transactions in the ordinary course of business, in or affecting: (A) the business, condition (financial or otherwise), results of operations, shareholders’ equity, properties or prospects of the Company; (B) the long-term debt or capital stock of the Company; or (C) the Offering or consummation of any of the other transactions contemplated by this Agreement, the Representative Warrant, the Registration Statement, the General Disclosure Package and the Prospectus (a “**Material Adverse Change**”). Since the date of the latest balance sheet presented in the Registration Statement, the General Disclosure Package and the Prospectus, the Company has not incurred or undertaken any liabilities or obligations, whether direct or indirect, liquidated or contingent, matured or unmatured, or entered into any transactions, including any acquisition or disposition of any business or asset, which are material to the Company, except (I) for liabilities, obligations and transactions which are disclosed in the Registration Statement, the General Disclosure Package and the Prospectus and (II) as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

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(i) The Company has an authorized capitalization as set forth in the Registration Statement, the General Disclosure Package and the Prospectus in the column headed “Actual” under the section thereof captioned “Capitalization;” all of the issued shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and nonassessable and have been issued in compliance in all material respects with all applicable federal and state securities laws and none of those shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights of any securityholder of the Company that have not been otherwise waived (with copies of such waivers, if any, made available to the Underwriters); the Securities have been duly authorized and, when



issued and delivered against payment therefore as provided in this Agreement, will be validly issued, fully paid and non-assessable, and the issuance of the Securities is not subject to any preemptive rights, rights of first refusal or other similar rights that have not heretofore been waived (with copies of such waivers, if any, made available to the Underwriters); and, to the Company's knowledge, no holder of any Securities will be subject to personal liability by reason of being such a holder. The Securities and the Representative's Warrants conform in all material respects to the descriptions thereof contained in the Registration Statement, the General Disclosure Package and the Prospectus.

(j) Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, or as otherwise contemplated by this Agreement, (A) there are no outstanding rights (contractual or otherwise), warrants or options to acquire, or instruments convertible into or exchangeable for, or agreements or understandings made by the Company with respect to the sale or issuance of, any shares of capital stock of or other equity interest in the Company, and (B) there are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act or otherwise register any securities of the Company owned or to be owned by such person and any such rights so disclosed have been waived by the holders thereof in connection with this Agreement and the transactions contemplated hereby including the Offering.

(k) The shares of Common Stock underlying the Representative's Warrants have been duly authorized and validly reserved for issuance, conform to the description thereof in the Registration Statement, the General Disclosure Package and the Prospectus and will, upon exercise of the Representative's Warrants and payment of the exercise price thereof, be duly and validly issued, fully paid and non-assessable and will not have been issued in violation of or be subject to preemptive or similar rights to subscribe for or purchase securities of the Company and, to the Company's knowledge, the holders thereof will not be subject to personal liability by reason of being such holders.

(l) The Company does not have any subsidiaries.

(m) The Company has been duly incorporated and validly exists as a corporation, in good standing under the laws of the State of Delaware. The Company has all requisite power and authority to carry on its business as it is currently being conducted and as described in the Registration Statement, the General Disclosure Package and the Prospectus, and to own, lease and operate its properties. The Company is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the character or location of its properties (owned, leased or licensed) or the nature or conduct of its business makes such qualification

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necessary, except, in each case, for those failures to be so qualified or in good standing which (individually or in the aggregate) would not reasonably be expected to result in a Material Adverse Change.

(n) The Company is not: (i) in violation of its certificate of incorporation or bylaws or other organizational documents, (ii) in default under any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which it is a party or by which it is bound or to which any of its property or assets is subject; and no event has occurred which, with notice or lapse of time or both, would constitute a default under or result in the creation or imposition of any lien, security interest, charge or other encumbrance (a "Lien") upon any of its property or assets pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which it is a party or by which it is bound or to which any of its property or assets is subject, or (iii) in violation in any respect of any law, rule, regulation, ordinance, directive, judgment, decree or order of any judicial, regulatory or other legal or governmental agency or body, foreign or domestic, except, in the case of subsections (ii) and (iii) above, for such violations, defaults or Liens which (individually or in the aggregate) would not reasonably be expected to result in a Material Adverse Change.

(o) When issued, the Representative's Warrants will constitute the valid and binding obligations of the Company to issue and sell, upon exercise thereof and payment of the respective exercise prices therefor, the number and type of securities of the Company called for thereby in accordance with the terms thereof and such Representative's Warrants are enforceable against the Company in accordance with their respective terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under foreign, federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(p) The execution, delivery, and performance of this Agreement, the Representative's Warrants and all other agreements, documents, certificates and instruments required to be delivered pursuant to this Agreement, and the Representative's Warrants and consummation of the transactions contemplated hereby and thereby do not and will not: (i) conflict with, require consent under or result in a breach of any of the terms and provisions of, or constitute a default (or an event which with notice or lapse of time, or both, would constitute a default) under, or result in the creation or imposition of any Lien upon any property or assets of the Company pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement, instrument, franchise, license or permit to which the Company is a party or by which the Company or any of its properties, operations or assets may be bound or (ii) violate or conflict with any provision of the certificate of incorporation, by-laws, or other organizational documents of the Company, or (iii) violate or conflict with any law, rule, regulation, ordinance, directive, judgment, decree or order of any judicial, regulatory or other legal or governmental agency or body, domestic or foreign, or (iv) trigger a reset or repricing of any outstanding securities of the Company, except in the case of subsections (i) and (iii) for any default, conflict, Lien or violation that would not have or could reasonably be expected to result in a Material Adverse Change, and in the case of subsection (i) regarding consent, except for such consents as may have previously been obtained (with copies of such consents, if any, made available to the Underwriters).

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(q) The Company has all consents, approvals, authorizations, orders, registrations, qualifications, licenses, filings and permits of, with and from all judicial, regulatory and other legal or governmental agencies and bodies and all third parties, foreign and domestic (collectively, the “**Consents**”), to own, lease and operate its properties and conduct its business as it is now being conducted and as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, and each such Consent is valid and in full force and effect, except which (individually or in the aggregate), in each such case, would not reasonably be expected to result in a Material Adverse Change. The Company has not received notice (whether written or, to the Company’s knowledge, verbal) of any investigation or proceedings which results in or, if decided adversely to the Company could reasonably be expected to result in, the revocation of, or imposition of a restriction on, any Consent, except such restriction or revocation of such Consent which (individually or in the aggregate), in each such case, would not reasonably be expected to result in a Material Adverse Change. No Consent contains any material restriction that has not been adequately disclosed in the Registration Statement, the General Disclosure Package and the Prospectus.

(r) The Company has filed with the Commission a Form 8-A (File Number [ ]) providing for the registration of the Common Stock (the “**Form 8-A Registration Statement**”). The Common Stock is registered pursuant to Section 12(b) under the Exchange Act. The Form 8-A Registration Statement was declared effective by the Commission on or prior to the date hereof. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration.

(s) The Common Stock has been approved for listing on the NASDAQ Capital Market (the “**Exchange**”) subject to notice of issuance on the Exchange, and the Company has taken no action designed to, or likely to have the effect of, delisting the shares of Common Stock from the Exchange, nor has the Company received any notification that the Exchange is contemplating terminating such listing.

(t) No consent of, with or from any judicial, regulatory or other legal or governmental agency or body or any third party, foreign or domestic is required for the execution, delivery and performance of this Agreement, the Representative’s Warrants or consummation of each of the transactions contemplated by this Agreement, including the issuance, sale and delivery of the Securities to be issued, sold and delivered hereunder, except (i) such as may have previously been obtained (with copies of such consents, if any, made available to the Underwriters), (ii) the registration under the Securities Act of the Securities, which has become effective, (iii) such consents as may be required under state securities or blue sky laws or the by-laws and rules of the Exchange, and (iv) by FINRA in connection with the purchase and distribution of the Securities by the Underwriters, each of which has been obtained and is in full force and effect.

(u) Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, there is no judicial, regulatory, arbitral or other legal or governmental proceeding or other litigation or arbitration, domestic or foreign, pending to which the Company is a party or of which any property, operations or assets of the Company is the subject which, individually or in the aggregate, if determined adversely to the Company, would reasonably be

expected to result in a Material Adverse Change. To the Company’s knowledge, no such proceeding, litigation or arbitration is threatened or contemplated.

(v) The financial statements, including the notes thereto, and the supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus comply in all material respects with the requirements of the Securities Act and the Exchange Act, and present fairly the financial position as of the dates indicated and the cash flows and results of operations for the periods specified of the Company. Except as otherwise stated in the Registration Statement, the General Disclosure Package and the Prospectus, such financial statements have been prepared in conformity with United States generally accepted accounting principles (“**GAAP**”) applied on a consistent basis throughout the periods involved, except in the case of unaudited financials which are subject to normal year end adjustments and do not contain certain footnotes. The supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly the information required to be stated therein. No other financial statements or supporting schedules are required to be included in the Registration Statement, the General Disclosure Package or the Prospectus. The other financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly the information included therein and have been prepared on a basis consistent with that of the financial statements that are included in the Registration Statement, the General Disclosure Package and the Prospectus and the books and records of the Company. There are no material off-balance sheet arrangements (as defined in item 303 of Regulation S-K).

(w) There are no pro forma or as adjusted financial statements which are required to be included in the Registration Statement, the General Disclosure Package and the Prospectus in accordance with Regulation S-X which have not been included as so required. The pro forma and pro forma as adjusted financial information included in the Registration Statement, the General Disclosure Package and the Prospectus have been properly compiled and prepared in all material respects in accordance with the applicable requirements of the Securities Act and the Rules and Regulations and include all adjustments necessary to present fairly in accordance with GAAP the pro forma and pro forma as adjusted financial position of the Company at the respective dates indicated and the Company’s cash flows and the results of operations for the respective periods specified. The assumptions used in preparing the pro forma and pro forma as adjusted financial information included in the Registration Statement, the General Disclosure Package and the Prospectus provide a reasonable basis for presenting the significant effects directly attributable to the transactions or events described therein. The related pro forma and pro forma as adjusted adjustments give appropriate effect to those assumptions; and the pro forma and pro forma as adjusted financial information reflect the proper application of those adjustments to the corresponding historical financial

statement amounts.

(x) The statistical, industry-related and market-related data included in the Registration Statement, the General Disclosure Package and the Prospectus are based on or derived from sources which the Company reasonably and in good faith believes are reliable and accurate, and such data agrees with the sources from which they are derived. The Company is not required under the Securities Act and the Rules and Regulations to obtain any written consents to use such data from such sources.

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(y) The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-14 and 15d-14 under the Exchange Act) and such controls and procedures are designed to ensure that the information relating to the Company is made known to the principal executive officer and the principal financial officer. The Company maintains a system of internal accounting controls designed to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorizations; (B) transactions are recorded as necessary to permit the preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorizations; and (D) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Since the date of the Company's most recent audited balance sheet included in the Registration Statement, the General Disclosure Package and the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(z) Neither the board of directors nor the audit committee has been informed, nor is any executive officer of the Company aware, of: (i) any significant deficiencies and material weaknesses in the design or operation of the Company's internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; or (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

(aa) Neither the Company nor any of its Affiliates (as defined in the Securities Act) has taken, directly or indirectly, any action which constitutes or is designed to cause or result in, or which could reasonably be expected to constitute, cause or result in, the stabilization or manipulation of the price of any security to facilitate the sale or resale of the Securities; provided, however, the Company makes no such representation or warranty with respect to actions of any Underwriter or any Affiliate or agent of any Underwriter.

(bb) Neither the Company nor any of its Affiliates has, prior to the date hereof, made any offer or sale of any securities which are required to be "integrated" pursuant to the Securities Act or the Rules and Regulations with the offer and sale of the Securities pursuant to the Registration Statement. Except as disclosed in the Registration Statement, the General Disclosure Package, and the Prospectus, neither the Company nor any of its Affiliates has sold or issued any securities during the six-month period preceding the date of the Prospectus, including but not limited to any sales pursuant to Rule 144A or Regulation D or Regulation S under the Securities Act, other than shares of Common Stock issued pursuant to employee benefit plans, qualified stock option plans or employee compensation plans or pursuant to outstanding options, rights or warrants.

(cc) To the knowledge of the Company, all information contained in the questionnaires completed by each of the Company's officers, directors and 5% holders immediately prior to the Offering and provided to the Representative as well as the biographies of such officers and directors in the Registration Statement are true and correct in all material respects and the Company has not become aware of any information which would cause the

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information disclosed in the questionnaires completed by the directors and officers to become inaccurate and incorrect in any material respect.

(dd) To the knowledge of the Company, no director or officer of the Company is subject to any non-competition agreement or non-solicitation agreement with any employer or prior employer which could materially affect his or her ability to be and act in his or her respective capacity of the Company.

(ee) The Company is not and, at all times up to and including consummation of the transactions contemplated by this Agreement, and after giving effect to application of the net proceeds of the Offering, will not be, subject to registration as an "investment company" under the Investment Company Act of 1940, as amended, and is not and will not be an entity "controlled" by an "investment company" within the meaning of such act.

(ff) No relationship, direct or indirect, exists between or among any of the Company or, to the knowledge of the Company, any Affiliate of the Company, on the one hand, and any director, officer, shareholder, customer or supplier of the Company or, to the knowledge of the Company, any Affiliate of the Company, on the other hand, which is required by the Securities Act, the Exchange Act or the Rules and Regulations to be described in the Registration Statement or the Prospectus which is not so described as required. There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees of indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of their respective family members, except as described in the Registration Statement, the General Disclosure Package and the Prospectus. The Company has not, in violation of Sarbanes-Oxley directly or indirectly extended or maintained credit, arranged for the extension of credit, or renewed an extension of credit, in the form of a personal loan to or for any director or executive officer of the Company.

(gg) The Company is in compliance with the rules and regulations promulgated by the Exchange (to the extent applicable to the Company prior to the listing of the Common Stock on the Exchange), except for such violations which, individually or in the aggregate, would not result in a Material Adverse Change.

(hh) [INTENTIONALLY OMITTED.]

(ii) The Company owns or leases all such properties (other than intellectual property, which is covered by Section 2(jj)) as are necessary to the conduct of its business as presently operated as described in the Registration Statement, the General Disclosure Package and the Prospectus. The Company has good and marketable title in fee simple to all real property and good and marketable title to all personal property owned by it, in each case free and clear of all Liens except such as are described in the Registration Statement, the General Disclosure Package and the Prospectus or such as do not (individually or in the aggregate) or that do not, individually or in the aggregate, materially affect the value of such property and do not materially interfere with the use made of such property by the Company. Any real property and buildings held under lease or sublease by the Company are held by it under valid, subsisting and enforceable leases with such exceptions as are not material to, and do not materially interfere with, the use made and proposed to be made of such property and buildings by the Company. The Company has not

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received any notice (whether written or verbal) of any claim adverse to its ownership of any real or personal property or of any claim against the continued possession of any real property, whether owned or held under lease or sublease by the Company except for such claims which, if successfully asserted against the Company, would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

(jj) The Company: (i) owns, possesses, or has the right to use all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, formulae, customer lists, and know-how and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures, "**Intellectual Property**") necessary for the conduct of its businesses as being conducted and as described in the Registration Statement, the General Disclosure and Prospectus, and (ii) has no knowledge that such conduct of its business conflicts or will conflict with the rights of others, and it has not received any written notice of any claim of conflict with any right of others. Except as set forth in the Registration Statement, the General Disclosure Package or the Prospectus, the Company has not granted or assigned to any other Person any right to sell any of the products or services of the Company. To the Company's knowledge, (A) there is no infringement by third parties of any such Intellectual Property; (B) there is no pending or threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any such Intellectual Property; and (C) there are no facts which would form a reasonable basis for any such claim set forth in subsection (B) of this Section 2(jj). There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any intellectual property rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such claim. The Company has taken commercially reasonable security measures to protect the secrecy, confidentiality and value of all of its Intellectual Property. The Company, and to the Company's knowledge its patent counsel, have complied with the duty of candor and good faith in dealing with the U.S. Patent and Trademark Office and any similar duties in dealing with similar foreign intellectual property offices. To the Company's knowledge, there are no material defects in the preparation and filing of any of the Company's patents and patent applications. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company has not received any claim for royalties or other compensation from any Person, including any employee of the Company who made inventive contributions to Company's technology or products that are pending or unsettled, and except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus the Company does not and will not have any obligation to pay royalties or other compensation to any Person on account of inventive contributions.

(kk) The agreements and documents described in the Registration Statement, the General Disclosure Package and the Prospectus conform in all material respects to the descriptions thereof contained therein and there are no agreements or other documents required by the applicable provisions of the Securities Act to be described in the Registration Statement, the General Disclosure Package or the Prospectus or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other document (however characterized or described) to which the Company is a party or by which its property or business is or may be bound or affected and (i) that is referred to in the Registration Statement, the General Disclosure Package or the Prospectus or attached as an exhibit thereto, or

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(ii) is material to the Company's business, has been duly and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the foreign, federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought, and none of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the Company's knowledge, any other party is in material breach or default thereunder and, to the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a breach or default thereunder, in any such case, which would result in a Material Adverse Change.

(ll) No securities of the Company have been sold by the Company or by or on behalf of, or for the benefit of, any person

or persons controlling, controlled by, or under common control with the Company since the date of the Company's formation, except as required to be disclosed in the Registration Statement, the General Disclosure Package and the Prospectus.

(mm) The disclosures in the Registration Statement, the General Disclosure Package and the Prospectus concerning the effects of federal, state and local regulation on the Company's business as currently contemplated are correct in all material respects and do not omit to state a material fact necessary to make the statements therein, in light of the circumstances in which they were made, not misleading.

(nn) The Company has accurately prepared and timely filed all federal, state and other tax returns that are required to be filed by it, except where the failure so to file would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change, and has paid or made provision for the payment of all material taxes, assessments, governmental or other similar charges, including without limitation, all sales and use taxes and all taxes which the Company is obligated to withhold from amounts owing to employees, creditors and third parties, with respect to the periods covered by such tax returns, whether or not such amounts are shown as due on any tax return (except as currently being contested in good faith and for which reserves required by GAAP have been created in the financial statements of the Company) GAAP and except for such taxes, assessments, governmental or other similar charges the nonpayment of which would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change. No deficiency assessment with respect to a proposed adjustment of the Company's federal, state, local or foreign taxes is pending or, to the Company's knowledge, threatened. There is no tax lien, whether imposed by any federal, state, foreign or other taxing authority, outstanding against the assets, properties or business of the Company.

(oo) No labor disturbance or dispute by or with the employees of the Company which, individually or in the aggregate, would reasonably be expected to result in a Material Adverse Change, currently exists or, to the Company's knowledge, is threatened. The Company is in compliance in all material respects with the labor and employment laws applicable to its employees.

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(pp) Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, and would not be reasonably expected, individually or in the aggregate, to result in a Material Adverse Change, the Company has at all times operated its business in material compliance with all material Environmental Laws (as hereinafter defined), and no material expenditures are or will be required in order to comply therewith. The Company has not received any notice (whether written or, to the Company's knowledge, verbal) or communication that relates to or alleges any actual or potential violation or failure to comply with any Environmental Laws that would, individually or in the aggregate, be reasonably expected to result in a Material Adverse Change. As used herein, the term "**Environmental Laws**" means all applicable laws and regulations, including any licensing, permits or reporting requirements, and any action by a federal state or local government entity pertaining to the protection of the environment, protection of public health, protection of worker health and safety, or the handling of hazardous materials, including without limitation, the Clean Air Act, 42 U.S.C. § 7401, et seq., the Comprehensive Environmental Response, Compensation and Liability Act of 1980, 42 U.S.C. § 9601, et seq., the Federal Water Pollution Control Act, 33 U.S.C. § 1321, et seq., the Hazardous Materials Transportation Act, 49 U.S.C. § 1801, et seq., the Resource Conservation and Recovery Act, 42 U.S.C. § 690-1, et seq., and the Toxic Substances Control Act, 15 U.S.C. § 2601, et seq.

(qq) As to each product candidate subject to the jurisdiction of the U.S. Food and Drug Administration ("**FDA**") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("**FDCA**") and/or the jurisdiction of the non-U.S. counterparts thereof that is studied, by the Company (each such product, a "**Product**"), such Product is being studied by the Company in compliance with all applicable requirements under FDCA and/or similar laws, rules and regulations relating to, among others, investigational use, good manufacturing practices, good laboratory practices, good clinical practices, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Change. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company currently has no products that have been approved by the FDA or any non-U.S. counterparts thereof to be (i) manufactured, packaged, labeled, and/or distributed for sale and/or marketing or (ii) sold and/or marketed. To the Company's knowledge, there is no pending, completed or, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory or disciplinary proceeding, charge, complaint, or investigation) against the Company and the Company has not received any notice, warning letter or other communication from the FDA or any other governmental entity or any non-U.S. counterparts thereof, which (i) contests the investigational use of, manufacturing or packaging of, the study of, or the labeling of any Product, (ii) requests the recall, suspension, or seizure of any Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any principal investigator, (iv) enjoins production at any facility of the Company, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company, (vi) debars or suspends, proposes for debarment, or declares ineligible any Company executive, director, employee or personnel, or (vii) otherwise alleges any violation of any laws, rules or regulations by the Company, and which, either individually or in the aggregate, would have a Material Adverse Change. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA and non-U.S. counterparts thereof. The Company has not been informed by the FDA or any non-U.S. counterparts thereof that such agency will prohibit the marketing, distribution, sale, or use of any

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Product nor has the FDA or a non-U.S. counterpart thereof provided any written notice that could reasonably be expected to preclude the approval for marketing and sale of any Product.

(rr) The clinical, pre-clinical and other studies and tests conducted by or on behalf of or sponsored by the Company that are described or referred to in the Registration Statement, the General Disclosure Package and the Prospectus were and, if still pending, are being conducted in accordance with all statutes, laws, rules and regulations, as applicable (including, without limitation, those

administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA), except where the failure to be so conducted would not have a Material Adverse Change. The descriptions of the results of such studies and tests that are described or referred to in the Registration Statement, the General Disclosure Package and the Prospectus are accurate and complete in all material respects and fairly present the data derived from such studies and tests, and the Company has no knowledge of other material studies or tests the results of which are materially inconsistent with or otherwise materially call into question the results described or referred to in the Registration Statement, the General Disclosure Package and the Prospectus. The Company has not received any notices or other correspondence from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA with respect to any ongoing clinical or pre-clinical studies or tests requiring the termination or suspension of such studies or tests. For the avoidance of doubt, the Company makes no representation or warranty that the results of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company will be sufficient to obtain governmental approval from the FDA or any foreign, state or local governmental body exercising comparable authority or that additional studies, tests or preclinical or clinical trials will reach similar results or conclusions.

(ss) Except as would not result in a Material Adverse Change, the Company has not failed to file with the applicable regulatory authorities (including the FDA or any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) any filing, declaration, listing, registration, report or submission that is required to be so filed for the Company's business operation as currently conducted. All such filings were in material compliance with applicable laws and regulations when filed and no material deficiencies have been asserted in writing by any applicable regulatory authority (including, without limitation, the FDA or any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) with respect to any such filings, declarations, listings, registrations, reports or submissions. The Company holds, and is in compliance with, all franchises, grants, authorizations, licenses, permits, easements, consents, certificates and orders ("**Permits**") of any governmental or self-regulatory agency, authority or body (including, without limitation, those administered by FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) required for the conduct of the Company's business as currently conducted, and all such Permits are in full force and effect, in each case except where the failure to hold, or comply with, any of them is not reasonably likely to result in a Material Adverse Change.

(tt) To the extent required by Form S-1 promulgated under the Securities Act, the Registration Statement, the General Disclosure Package and the Prospectus identify each

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employment, severance or other similar agreement, arrangement or policy and each material arrangement providing for insurance coverage, benefits, bonuses, stock options, or other forms of incentive compensation, or post-retirement insurance, compensation or benefits which: (i) is entered into, maintained or contributed to, as the case may be, by the Company and (ii) covers any officer or director or former officer or former director of the Company. These contracts, plans and arrangements are referred to collectively in this Agreement as the "**Benefit Arrangements**." Each Benefit Arrangement has been maintained in substantial compliance with its terms and with requirements prescribed by any and all statutes, orders, rules and regulations that are applicable to that Benefit Arrangement in each case except where the failure to comply is not reasonably likely to result in a Material Adverse Change.

(uu) There are no business relationships or related party transactions involving the Company or, to the knowledge of the Company, any other person that are required to be described in the Registration Statement, the General Disclosure Package or the Prospectus that have not been described as required.

(vv) The conditions for use of Form S-1 to register the Offering under the Securities Act, as set forth in the General Instructions to such Form, have been satisfied.

(ww) Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, neither the execution of this Agreement or the Representative's Warrants nor the consummation of the Offering constitutes a triggering event under any Benefit Arrangement or any other employment contract, whether or not legally enforceable, which will or may result in any payment (of severance pay or otherwise), acceleration, increase in vesting, or increase in benefits to any current or former participant, employee or director of the Company other than an event that is not material to the financial condition or business of the Company.

(xx) Neither the Company nor, to the Company's knowledge, any of its employees or agents has at any time during the last three (3) years: (i) made any unlawful contribution to any candidate for foreign office, or failed to disclose fully any contribution in violation of law, or (ii) made any payment to any federal or state governmental officer or official or other Person charged with similar public or quasi-public duties in the United States, in each case other than payments that are not prohibited by the laws of the United States or any jurisdiction thereof.

(yy) Neither the Company nor, to the Company's knowledge, any of its officers, directors, employees or Affiliates has offered, or caused the Underwriters to offer, the Securities to any Person or entity with the intention of unlawfully influencing: (i) a customer or supplier of the Company to alter the customer's or supplier's level or type of business with the Company or (ii) a journalist or publication to write or publish favorable information about the Company, or its products or services.

(zz) The operations of the Company are and have been conducted at all times in compliance in all material respects with applicable financial record keeping and reporting requirements and money laundering statutes of the United States and, to the Company's knowledge, all other applicable jurisdictions to which the Company is subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any applicable governmental agency (collectively, the "**Money**")

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**Laundering Laws**”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(aaa) Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee or Affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department (“**OFAC**”); and the Company will not directly or indirectly use the proceeds of the Offering, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(bbb) Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company has engaged in any activities sanctionable under the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, the Iran Sanctions Act of 1996, the National Defense Authorization Act for Fiscal Year 2012, the Iran Threat Reduction and Syria Human Rights Act of 2012 or any Executive Order relating to any of the foregoing (collectively, and as each may be amended from time to time, the “**Iran Sanctions**”); and the Company will not directly or indirectly use the proceeds of the Offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of engaging in any activities sanctionable under the Iran Sanctions.

(ccc) Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, (i) the Company does not have any lending or similar relationship with any Underwriter or any bank or other lending institution affiliated with any Underwriter; (ii) the Company will not, directly or indirectly, use any of the proceeds from the sale of the Securities by the Company hereunder to reduce or retire the balance of any loan or credit facility extended by any Underwriter or any of its “affiliates” or “associated persons” (as such terms are used in FINRA Rule 5121) or otherwise direct any such proceeds to any Underwriter or any of its “affiliates” or “associated persons” (as so defined); and (iii) there are and have been no transactions, arrangements or dealings between the Company, on the one hand, and any Underwriter or any of its “affiliates” or “associated persons” (as so defined), on the other hand, that, under FINRA Rule 5110 or 5121, must be disclosed in a submission to FINRA in connection with the offering of the Securities contemplated hereby or disclosed in the Registration Statement, the General Disclosure Package or Prospectus that have not otherwise been disclosed by the Company.

(ddd) [INTENTIONALLY OMITTED.]

(eee) Since that date of the Preliminary Prospectus included in the Registration Statement first submitted to the Commission on December 20, 2013 (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication (as defined herein)) through the date hereof, the Company has been and is an “emerging growth company,” as defined in Section 2(a) of the Securities Act (an “**Emerging Growth Company**”). “**Testing-the-Waters Communication**”

means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(fff) The Company (a) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representative with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (b) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Underwriters have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications (as defined herein) other than those listed on Schedule IV hereto. “**Written Testing-the-Waters Communication**” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(ggg) At the time of filing the Registration Statement, any Rule 462(b) Registration Statement, and any post-effective amendments thereto, and at the date hereof, the Company was not, and the Company currently is not, an “ineligible issuer” as defined in Rule 405 of the Rules and Regulations.

(hhh) As used in this Agreement, the term “**knowledge of the Company**” (or similar language) shall mean the actual knowledge of the executive officers and directors of the Company who are named in the Prospectus, with the assumption that such executive officers and directors shall have made a reasonable inquiry of the matters presented.

(iii) Any certificate signed by or on behalf of the Company and delivered to the Underwriters or to Loeb & Loeb LLP (“**Underwriters’ Counsel**”) shall be deemed to be a representation and warranty by the Company to each Underwriter listed on Schedule I hereto as to the matters covered thereby.

(jjj) The Second Amended and Restated Investors’ Rights Agreement, dated July 11, 2014 (as amended, the “**Investors’ Rights Agreement**”), is in full force and effect. Each holder of all series of the Company’s preferred stock is a signatory to the Investors’ Rights Agreement. The Investors’ Rights Agreement shall remain in full force and effect for a period of no less than 180 days after the Effective Date, unless otherwise consented to by the Representative.

3. **Offering.** Upon authorization of the release of the Securities by the Representative, the Underwriters propose to offer the Securities for sale to the public upon the terms and conditions set forth in the Prospectus.

4. Covenants of the Company. The Company acknowledges, covenants and agrees with the Representative that:

(a) The Registration Statement and any amendments thereto have been declared effective, and if Rule 430A is used or the filing of the Prospectus is otherwise required under Rule 424(b), the Company will file the Prospectus (properly completed if Rule 430A has been used) pursuant to Rule 424(b) within the prescribed time period and will provide evidence satisfactory to the Representative of such timely filing.

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(b) During the period beginning on the date hereof and ending on the later of the Closing Date or such date as, in the reasonable opinion of Underwriters' Counsel, the Prospectus is no longer required by law to be delivered (or in lieu thereof the notice referred to in Rule 173(a) under the Securities Act is no longer required to be provided), in connection with sales by an underwriter or dealer (the "**Prospectus Delivery Period**"), prior to amending or supplementing the Registration Statement, the General Disclosure Package or the Prospectus, the Company shall furnish to the Representative for review a copy of each such proposed amendment or supplement, and the Company shall not file any such proposed amendment or supplement to which the Representative reasonably objects in writing within 36 hours of delivery thereof to the Representative and its counsel.

(c) After the date of this Agreement, the Company shall promptly advise the Representative in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission, (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to any prospectus, the General Disclosure Package or the Prospectus, (iii) of the time and date that any post-effective amendment to the Registration Statement becomes effective, and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto or of any order preventing or suspending its use or the use of any prospectus, the General Disclosure Package, the Prospectus or any Issuer-Represented Free Writing Prospectus, or of any proceedings to remove, suspend or terminate from listing the Common Stock from any securities exchange upon which they are listed for trading, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its commercially reasonable efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with the provisions of Rules 424(b), 430A and 430B, as applicable, under the Securities Act and will use its commercially reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission (without reliance on Rule 424(b)(8) or Rule 164(b)).

(d) (i) During the Prospectus Delivery Period, the Company will comply in all material respects with all requirements imposed upon it by the Securities Act, as now and hereafter amended, and by the Rules and Regulations, as from time to time in force, and by the Exchange Act so far as reasonably necessary to permit the continuance of sales of or dealings in the Securities as contemplated by the provisions hereof, the General Disclosure Package, the Registration Statement and the Prospectus. If during such period any event occurs as a result of which the Prospectus (or if the Prospectus is not yet available to prospective purchasers, the General Disclosure Package ) would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary or appropriate in the reasonable opinion of the Company or its counsel or the Representative or Underwriters' Counsel to amend the Registration Statement or supplement the Prospectus (or if the Prospectus is not yet available to prospective purchasers, the General Disclosure Package ) to comply with the Securities Act or to file under the Exchange Act any document which would be deemed to be incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, the Company will promptly notify the Representative and will amend the

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Registration Statement or supplement the Prospectus (or if the Prospectus is not yet available to prospective purchasers, the General Disclosure Package) or file such document (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(ii) If at any time following issuance of an Issuer-Represented Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer-Represented Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement, the Statutory Prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company has promptly notified or promptly will notify the Representative and has promptly amended or will promptly amend or supplement, at its own expense, such Issuer-Represented Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(e) The Company has delivered or will promptly deliver to the Underwriters and Underwriters' Counsel a signed copy of the Registration Statement, as initially filed and all amendments thereto, including all consents and exhibits filed therewith, and will maintain in the Company's files manually signed copies of such documents for at least five (5) years after the date of filing thereof. The Company has delivered or will promptly deliver to each of the Underwriters such number of copies of any Preliminary Prospectus, the Prospectus, the Registration Statement, and all amendments of and supplements to such documents, if any, and all documents which are exhibits to the Registration Statement and Prospectus or any amendment thereof or supplement thereto, as the Underwriters may reasonably request. Prior to 10:00 a.m., New York time, on the Business Day next succeeding the date of this Agreement and from time to time thereafter, the Company will furnish the Underwriters with copies of the Prospectus in New York City or such other location as reasonably acceptable to the Underwriters in such quantities as the Underwriters may reasonably request.



(f) The Company consents to the use and delivery of the Preliminary Prospectus by the Underwriters in accordance with Rule 430 and Section 5(b) of the Securities Act.

(g) If the Company elects to rely on Rule 462(b) under the Securities Act, the Company shall both file a Rule 462(b) Registration Statement with the Commission in compliance with Rule 462(b) and pay the applicable fees in accordance with Rule 111 of the Securities Act by the earlier of: (i) 10:00 p.m., New York City time, on the date of this Agreement, and (ii) the time that confirmations are given or sent, as specified by Rule 462(b)(2).

(h) The Company will use its commercially reasonable efforts, in cooperation with the Representative, at or prior to the time of effectiveness of the Registration Statement, to qualify the Securities for offering and sale under the securities laws relating to the offering or sale of the Securities of such jurisdictions, domestic or foreign, as the Representative may reasonably designate and to maintain such qualification in effect for so long as required for the distribution thereof (but in no event for a period to exceed one year from the date of this Agreement), except that in no event shall the Company be obligated in connection therewith to qualify as a foreign corporation or other entity or as a dealer in securities in any such jurisdiction,

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to execute a general consent to service of process in any such jurisdiction, or to subject itself to taxation in any such jurisdiction if it is otherwise not so subject.

(i) During the 180 day period following the Closing Date neither the Company nor any successor to the Company shall undertake any public or private offerings of any equity securities of the Company (including equity-linked securities) without the prior written consent of the Representative. Notwithstanding the provisions set forth in the immediately preceding sentence, the Company may, without the prior written consent of the Representative:

- (1) issue Securities to the Underwriters pursuant to this Agreement,
- (2) issue the Representative's Warrants and the Representative's Securities pursuant to the terms of the Representative's Warrants,
- (3) issue restricted Common Stock, shares of Common Stock, options to purchase shares of Common Stock and other securities convertible into shares of Common Stock, in each case pursuant to stock option plans, stock purchase or other equity incentive plans described in the General Disclosure Package and the Prospectus, as those plans are in effect on the date of this Agreement,
- (4) issue shares of Common Stock upon the exercise of stock options or other securities convertible into shares of Common Stock issued under stock option or other equity incentive plans referred to in clause (3) above, as those plans are in effect on the date of this Agreement,
- (5) issue shares of Common Stock upon the exercise of warrants or convertible securities outstanding on the date of this Agreement, and
- (6) issue shares of Common Stock pursuant to transactions described in the General Disclosure Package and the Prospectus, including the issuance of shares of Common Stock upon the conversion of the Company's preferred stock.

(j) During the 180 day period following the Closing Date, the Company will not file any registration statement relating to the offer or sale of any of the Company's securities, without the consent of the Representative, except for Form S-8 filed in connection with a Company stock option plan.

(k) Following the Closing Date, the Company and any of the individuals listed on Schedule III hereto (the "**Lock-Up Parties**"), subject to the exceptions set forth in the agreement substantially in the form attached hereto as Annex I, shall not sell or otherwise dispose of any securities of the Company, whether publicly or in a private placement during the period that their respective lock-up agreements are in effect. The Company will deliver to the Representative the agreements of the Lock-Up Parties to the foregoing effect prior to the date of this Agreement, which agreements shall be substantially in the form attached hereto as Annex I.

(l) If the Representative, in its sole discretion, agrees to release or waive the restrictions set forth in a lock-up letter described in Section 4(k) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver at

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least three Business Days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by (i) a press release substantially in the form of Annex V hereto through a major news service or (ii) any other method that satisfies the obligations described in FINRA Rule 5131(d)(2) at least two Business Days before the effective date of the release or waiver.

(m) The Company, at its expense, shall register with and, for a period of three (3) years after the Closing Date, keep current, its registration in the Standard & Poor's Corporation Records Services (including annual report information).

(n) For a period of at least three (3) years from the Effective Date, the Company shall retain a nationally recognized PCAOB registered independent public accounting firm reasonably acceptable to the Representative. The Representative acknowledges that the Auditor is acceptable to the Representative.

(o) The Company will not issue press releases or engage in any other publicity, without the Representative's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, for a period ending at 5:00 p.m. Eastern time on the first Business Day following the twenty-fifth (25th) day following the Closing Date, other than normal and customary releases issued in the ordinary course of the Company's business, or as required by law.

(p) The Company will retain a transfer agent for the Company's Common Stock reasonably acceptable to the Representative for a period of at least three (3) years following the Closing Date. The Representative acknowledges that American Stock Transfer Company is acceptable to the Representative.

(q) The Company will apply the net proceeds from the sale of the Securities as set forth under the caption "Use of Proceeds" in the Prospectus.

(r) The Company will use its commercially reasonable efforts to effect and maintain the listing of the Common Stock on the Nasdaq Stock Market, the NYSE, or the NYSE MKT, for at least three (3) years after the Closing Date.

(s) The Company will, and will cause its legal counsel and transfer agent to enforce the restriction on the sale and transfer of Company securities set forth in Section 2.11 of the Investors' Rights Agreement. Neither the Company, nor any of the Company's legal counsel will approve any request for removal of the legend on certificates evidencing such holders' shares or any other request by the holders signatory to the Investors' Rights Agreement, which request would or could result in a violation of Section 2.11. The Company shall send written instructions to its transfer agent that any such requests from holders received directly by the transfer agent should be rejected. Furthermore, the Company shall not agree to any amendment or waiver of Section 2.11 of the Investors' Rights Agreement, without the prior consent of the Representative.

(t) The Company will promptly notify the Representative if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the

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distribution of the Securities within the meaning of the Securities Act and (b) 180 days' following the date of this Agreement.

(u) If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(v) The Company, during the period when the Prospectus is required to be delivered under the Securities Act or the Exchange Act, will file all documents required to be filed with the Commission pursuant to the Securities Act, the Exchange Act and the Rules and Regulations within the time periods required thereby.

(w) The Company will use its commercially reasonable efforts to do and perform all things required by the Company to be done or performed prior to the Closing Date under this Agreement by the Closing Date, and to satisfy all conditions precedent to the delivery of the Securities.

(x) The Company will not take, and will use its commercially reasonable efforts to cause its Affiliates not to take, directly or indirectly, any action which constitutes or is designed to cause or result in, or which could reasonably be expected to constitute, cause or result in, the stabilization or manipulation of the price of any security to facilitate the sale or resale of the Securities.

(y) The Company shall cause to be prepared and delivered to the Representative, at its expense, within two (2) Business Days from the effective date of this Agreement, an Electronic Prospectus to be used by the Underwriters in connection with the Offering. As used herein, the term "Electronic Prospectus" means a form of prospectus, and any amendment or supplement thereto, that meets each of the following conditions: (i) it shall be encoded in an electronic format, satisfactory to the Representative in its reasonable discretion, that may be transmitted electronically by the other Underwriters to offerees and purchasers of the Securities for at least the period during which a Prospectus relating to the Securities is required to be delivered under the Securities Act; (ii) it shall disclose the same information as the paper prospectus and prospectus filed pursuant to EDGAR, except to the extent that graphic and image material cannot be disseminated electronically, in which case such graphic and image material shall be replaced in the electronic prospectus with a fair and accurate narrative description or tabular representation of such material, as appropriate; and (iii) it shall be in or convertible into a paper format or an electronic format, satisfactory to the Representative, that will allow recipients thereof to store and have continuously ready access to the prospectus at any future time, without charge to such recipients (other than any fee charged for subscription to the Internet as a whole and for on-line time).

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(z) The Company represents and agrees that, unless it obtains the prior written consent of the Representative, and the Representative represents and agrees that, unless it obtains the prior written consent of the Company, it has not made and will not make any offer relating to the Securities that would constitute an “issuer free writing prospectus,” as defined in Rule 433 under the Securities Act, or that would otherwise constitute a “free writing prospectus,” as defined in Rule 405 under the Securities Act, required to be filed with the Commission; provided that the prior written consent of the parties hereto shall be deemed to have been given in respect of the free writing prospectuses included in Schedule II. Any such free writing prospectus consented to by the Company and the Representative is hereinafter referred to as a “Permitted Free Writing Prospectus.” Each of the Company and the Representative represents that it has treated or agrees that it will treat each Permitted Free Writing Prospectus as an “issuer free writing prospectus,” as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely Commission filing where required, legending and record keeping.

(aa) The Company hereby grants the Representative the right of first refusal for a period of fifteen (15) months from the Effective Date to act as lead managing underwriter and sole bookrunner and/or lead placement agent with respect to any offering of public and private equity, equity-linked or debt offerings (excluding commercial bank debt and credit facility offerings) with at least 75% of the economics if the Company, any successor to the Company or any subsidiaries has elected to employ a banker with respect to such offering. The Representative shall be required to exercise such right of first refusal, if the Representative so elects, within ten (10) Business Days of the receipt of a notice from the Company outlining the proposed terms of an offering and if the Representative fails to accept in writing any such proposal within such ten (10) Business Day period, then the Representative will have no claim or right with respect to such offering. The Representative’s decision at any time upon receipt of such notice(s), not to exercise such right with respect to such offering, shall not result in the termination of such right of first refusal. The fifteen (15) month right of first refusal period shall not be extended without the prior written consent of the Company in its sole and absolute discretion, and if extended, shall not have a duration of more than three (3) years from the date of commencement of sales of the Shares pursuant to this Offering. It is understood and agreed that the Company and the Representative shall comply with the requirements of FINRA Rules 5110(f)(2)(D) and 5110(f)(2)(E) with respect to the right of first refusal described in this Section 4(aa).

(bb) For a period of six (6) months from the Effective Date, the Company, at its expense, shall, for the first month from the Effective Date, provide the Representative on a weekly basis a copy of the Company’s weekly transfer sheets and, following the first month from the Effective Date, upon the prior request of the Representative, the Company shall use its commercially reasonable efforts to provide to the Representative on a monthly basis a copy of the Company’s weekly transfer sheets from the previous month and securities positions listings.

5. Payment of Expenses.

- a) Whether or not the transactions contemplated by this Agreement, the Registration Statement and the Prospectus are consummated or this Agreement is terminated, the Company hereby agrees to pay all costs and expenses incident to the performance of its obligations hereunder including the following:
- i. all filing fees and communication expenses relating to the registration of the Securities to be sold in the Offering with the Commission and the filing of the offering materials with FINRA;
  - ii. all fees and expenses relating to the listing of the Securities on the Exchange;
  - iii. all fees, expenses and disbursements relating to the registration or qualification of the Securities under the “blue sky” securities laws of such states and other jurisdictions as Representative may reasonably designate;
  - iv. the costs of all mailing and printing of a reasonable quantity of the underwriting documents (including the Underwriting Agreement, any blue sky surveys and, if appropriate, any agreement among underwriters, selected dealers’ agreement, underwriters’ questionnaire and power of attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto as the Representative may reasonably deem necessary;
  - v. the costs of preparing, printing and delivering certificates representing the Securities;
  - vi. fees and expenses of the transfer agent for the Securities;
  - vii. stock transfer taxes, if any, payable upon the transfer of the Securities from the Company to the Representative;
  - viii. the fees and expenses of the Company’s accountants;
  - ix. and the fees and expenses of the Company’s legal counsel and other agents and representatives.
- b) The Company shall pay the Underwriters a non-accountable expense allowance in an amount equal to 1.5% of the gross proceeds from the sale of the Firm Shares in the Offering (the “**Expense Allowance**”), for certain of their expenses incurred relating to this Offering, such as background check fees, cost for book building, prospectus tracking and compliance software and expenses for the road show, but excluding any legal fees. In addition, the Company shall reimburse the Underwriters for their legal fees incurred relating to this Offering in an aggregate amount up to \$100,000 (the “**Legal Cost Reimbursement**”). The Representative, on behalf of itself and the Underwriters, acknowledge and agree that the sum of the Expense Allowance and the Legal Cost Reimbursement represents the maximum amount of fees, disbursements and expense incurred the Underwriters relating to the Offering for which the Company shall be responsible. The Company shall provide funds to pay all such fees, expenses and

disbursements the Expense Allowance and the Legal Cost Reimbursement at the Closing of the Offering.

Notwithstanding anything to the contrary in this Section 5, in the event that this Agreement is terminated by the Company, pursuant to Section 11(b) hereof, or subsequent to a Material Adverse Change, the Company will pay the out-of-pocket expenses actually incurred as allowed under FINRA Rule 5110 by the Underwriters through the date of such termination (including the Legal Cost Reimbursement) in an aggregate amount not to exceed \$100,000.

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6. Conditions of Underwriters' Obligations. The obligations of the Underwriters to purchase and pay for the Firm Shares or the Option Shares, as the case may be, as provided herein shall be subject to: (i) the accuracy of the representations and warranties of the Company herein contained, as of the date hereof and as of the Closing Date, (ii) the absence from any certificates, opinions, written statements or letters furnished to the Representative or to Underwriters' Counsel pursuant to this Section 6 of any misstatement or omission, (iii) the performance by the Company of its obligations hereunder that are required to be performed or satisfied prior to the applicable Closing Date, and (iv) each of the following additional conditions. For purposes of this Section 6, the terms "Closing Date" and "Closing" shall refer to the Closing Date for the Firm Shares or the Option Shares, as the case may be, and each of the foregoing and following conditions must be satisfied as of each Closing.

(a) The Registration Statement shall have become effective and all necessary regulatory or listing approvals shall have been received not later than 5:30 p.m., New York time, on the date of this Agreement, or at such later time and date as shall have been consented to in writing by the Representative. If the Company shall have elected to rely upon Rule 430A under the Securities Act, the Prospectus shall have been filed with the Commission in a timely fashion in accordance with the terms hereof and a form of the Prospectus containing information relating to the description of the Securities and the method of distribution and similar matters shall have been filed with the Commission pursuant to Rule 424(b) within the applicable time period; and, at or prior to the Closing Date or the actual time of the Closing, no stop order suspending the effectiveness of the Registration Statement or any part thereof, or any amendment thereof, nor suspending or preventing the use of the General Disclosure Package, the Prospectus or any Issuer Free Writing Prospectus shall have been issued; no proceedings for the issuance of such an order shall have been initiated or threatened; any request of the Commission for additional information (to be included in the Registration Statement, the General Disclosure Package, the Prospectus, any Issuer Free Writing Prospectus or otherwise) shall have been complied with to the Representative's satisfaction; and FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(b) The Representative shall not have reasonably determined, and advised the Company, that the Registration Statement, the General Disclosure Package or the Prospectus, or any amendment thereof or supplement thereto, or any Issuer Free Writing Prospectus, contains an untrue statement of fact which, in the Representative's reasonable opinion, is material, or omits to state a fact which, in the Representative's reasonable opinion, is material and is required to be stated therein or necessary to make the statements therein not misleading; provided, however, that if in the Representative's opinion such deficiency is curable Representative shall have given the Company reasonable notice of such deficiency and a reasonable chance to cure such deficiency.

(c) The Representative shall have received the written opinion and negative assurance letter of (i) Morgan, Lewis & Bockius LLP, the legal counsel for the Company, dated as of the Closing Date and addressed to the Representative substantially in the form attached hereto as Annex II and (ii) Zoelex PLLC, intellectual property counsel to the Company dated as of the Closing Date and addressed to the Representative substantially in the form attached hereto as Annex III.

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(d) The Representative shall have received a certificate of the Chief Executive Officer and Chief Financial Officer (or the person acting in such capacity) of the Company, dated as of each Closing Date to the effect that: (i) as of the date hereof and as of the applicable Closing Date, the representations and warranties of the Company set forth in Section 2 hereof are accurate in all material respects, (ii) as of the applicable Closing Date, all agreements, conditions and obligations of the Company to be performed or complied with hereunder on or prior thereto have been duly performed or complied with, (iii) the Company has not sustained any material loss or interference with their respective businesses, whether or not covered by insurance, or from any labor dispute or any legal or governmental proceeding, (iv) no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereof has been issued and no proceedings therefor have been initiated or, to the knowledge of the Company, threatened by the Commission and (v) subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus there has not been any Material Adverse Change or any development that would give rise to a Material Adverse Change, whether or not arising from transactions in the ordinary course of business.

(e) On the date of this Agreement and on the Closing Date, the Representative shall have received a "cold comfort" letter from the Auditor as of the date of delivery and addressed to the Representative and in form and substance reasonably satisfactory to the Representative and Underwriters' Counsel, confirming that they are independent certified public accountants with respect to the Company within the meaning of the Securities Act and the Rules and Regulations, and stating, as of the date of delivery (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Prospectus, as of a date not more than five (5) days prior to the date of such letter), the conclusions and findings of such firm with respect to the financial information and other financial matters contained in the Registration Statement and the Prospectus covered by such letter.

(f) Subsequent to the execution and delivery of this Agreement and prior to the Closing Date, except as set forth in the Registration Statement, the General Disclosure Package, the Prospectus, or any Issuer Free Writing Prospectus, there shall not have been any change in the capital stock or long-term debt of the Company or any change or development involving a change, whether or not arising from transactions in the ordinary course of business, in the business, condition (financial or otherwise), results of operations,

shareholders' equity or properties of the Company including but not limited to the occurrence of any fire, flood, storm, explosion, accident, act of war or terrorism or other calamity, the effect of which, in any such case described above, is, in the sole judgment of the Representative, so material and adverse as to make it impracticable or inadvisable to proceed with the Offering on the terms and in the manner contemplated in the Prospectus (exclusive of any supplement).

(g) Prior to the execution and delivery of this Agreement, the Representative shall have received a lock-up agreement from each Lock-Up Party, duly executed by the applicable Lock-Up Party, in each case substantially in the form attached hereto as Annex I.

(h) The Common Stock is registered under the Exchange Act and, as of the Closing Date, the Common Stock shall be listed and admitted and authorized for trading on the Exchange and satisfactory evidence of such action shall have been provided to the Representative in the

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Representative's reasonable discretion. The Company shall have taken no action specifically designed to, or reasonably likely to have the effect of terminating the registration of the Common Stock, under the Exchange Act or delisting or suspending from trading the Common Stock from the Exchange, nor has the Company received any written information suggesting that the Commission or the Exchange is contemplating terminating such registration of listing. The Securities shall be DTC eligible.

(i) FINRA shall have confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements.

(j) No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any federal, state or foreign governmental or regulatory authority that would, as of the Closing Date, prevent the issuance or sale of the Securities; and no injunction or order of any federal, state or foreign court shall have been issued that would, as of the Closing Date, prevent the issuance or sale of the Securities or materially and adversely affect the business or operations of the Company.

(k) The Company shall have furnished the Representative with a Certificate of Good Standing for the Company certified by the Secretary of State of Delaware as of a recent date.

(l) The Company shall have furnished the Representative and Underwriters' Counsel with such other certificates, opinions or other documents as they may have reasonably requested.

(m) Solely with respect to the Closing Date for the Firm Shares, there shall have been issued to the Representative, the Representative's Warrant in the form attached hereto as Annex IV.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as required by this Agreement (or is not otherwise waived in writing by the Representative), or if any of the certificates, opinions, written statements or letters furnished to the Representative or to Underwriters' Counsel pursuant to this Section 6 shall not be reasonably satisfactory in form and substance to the Representative and to Underwriters' Counsel, all obligations of the Underwriters hereunder may be cancelled by the Representative at, or at any time prior to, the consummation of the Closing. Notice of such cancellation shall be given to the Company in writing or by telephone. Any such telephone notice shall be confirmed promptly thereafter in writing.

## 7. Indemnification.

(a) The Company agrees to indemnify and hold harmless each Underwriter, its officers, directors and employees, and each Person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any losses, liabilities, claims, damages and expenses whatsoever as incurred (including but not limited to reasonable attorneys' fees and any and all reasonable expenses whatsoever incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, and any and all amounts paid in settlement of any claim or litigation), joint or several, to which they or any of them may become subject under the Securities Act, the Exchange Act or otherwise (including in settlement of any litigation if such settlement is effected with the written consent of the Company), insofar as such losses, liabilities, claims, damages or

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expenses (or actions in respect thereof) arise out of or are based upon (i) an untrue statement or alleged untrue statement of a material fact or the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, contained in (A) the Registration Statement, including the information deemed to be a part of the Registration Statement at the time of effectiveness and at any subsequent time pursuant to Rules 430A and 430B of the Rules and Regulations, the General Disclosure Package, the Prospectus, or any amendment or supplement thereto (including any documents filed under the Exchange Act and deemed to be incorporated by reference into the Prospectus), or (B) any Issuer Free Writing Prospectus, any Testing-the-Waters Communications or in any other materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities, and any road show or investor presentations made to investors by the Company (whether in person or electronically) (collectively "**Marketing Materials**") or (ii) in whole or in part upon any inaccuracy in the representations and warranties of the Company contained herein; or (iii) in whole or in part upon any failure of the Company to perform its obligations hereunder or under law; provided, however, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, any Preliminary Prospectus, the General Disclosure Package, the Prospectus, or any

such amendment or supplement thereto, any Issuer Free Writing Prospectus, any Testing the Waters Communications or any other Marketing Materials, in reliance upon and in conformity with the Underwriters' Information.

(b) Each Underwriter, severally and not jointly, shall indemnify and hold harmless the Company, each of the directors of the Company, each of the officers of the Company who shall have signed the Registration Statement, and each other Person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any losses, liabilities, claims, damages and expenses whatsoever as incurred (including but not limited to attorneys' fees and any and all expenses whatsoever incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, and any and all amounts paid in settlement of any claim or litigation), joint or several, to which they or any of them may become subject under the Securities Act, the Exchange Act or otherwise, insofar as such losses, liabilities, claims, damages or expenses (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, as originally filed or any amendment thereof, or any related Preliminary Prospectus or the Prospectus, or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that any such loss, liability, claim, damage or expense arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with the Underwriters' Information; provided, however, that in no case shall any Underwriter be liable or responsible for any amount in excess of the underwriting discount applicable to the Securities to be purchased by such Underwriter hereunder. The parties

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agree that such information provided by or on behalf of any Underwriter through the Representative consists solely of the material referred to in the last sentence of Section 2(a) hereof.

(c) Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of any claims or the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify each party against whom indemnification is to be sought in writing of the claim or the commencement thereof (but the failure so to notify an indemnifying party shall not relieve the indemnifying party from any liability which it may have under this Section 7 to the extent that it is not materially prejudiced as a result thereof and in any event shall not relieve it from any liability that such indemnifying party may have otherwise than on account of the indemnity agreement hereunder). In case any such claim or action is brought against any indemnified party, and it notifies an indemnifying party of the commencement thereof, the indemnifying party will be entitled to participate, at its own expense in the defense of such action, and to the extent it may elect by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided however, that counsel to the indemnifying party shall not (except with the written consent of the indemnified party) also be counsel to the indemnified party. Notwithstanding the foregoing, the indemnified party or parties shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such indemnified party or parties unless (i) the employment of such counsel shall have been authorized in writing by one of the indemnifying parties in connection with the defense of such action, (ii) the indemnifying parties shall not have employed counsel to have charge of the defense of such action within 30 days after notice of commencement of the action, (iii) the indemnifying party does not diligently defend the action after assumption of the defense in the indemnified parties reasonable judgment after providing five Business Days notice of such failure to diligently defend the action and such failure continues, or (iv) such indemnified party or parties, upon the written advice of counsel, shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party, or any of them, in conducting the defense of any such action or there may be legal defenses available to it or them which are different from or additional to those available to one or all of the indemnifying parties (in which case the indemnifying parties shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events such fees and expenses shall be borne by the indemnifying parties and shall be paid as incurred. In no event shall the indemnifying party be liable for the fees and expenses of more than one counsel (in addition to any local counsel) for the Underwriters. No indemnifying party shall, without the prior written consent of the indemnified parties, effect any settlement or compromise of, or consent to the entry of judgment with respect to, any pending or threatened claim, investigation, action or proceeding in respect of which indemnity or contribution may be or could have been sought by an indemnified party under this Section 7 or Section 8 hereof (whether or not the indemnified party is an actual or potential party thereto), unless (x) such settlement, compromise or judgment (i) includes an unconditional release of the indemnified party from all liability arising out of such claim, investigation, action or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or any failure to act, by or on behalf of the indemnified party, and (y) the indemnifying party

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confirms in writing its indemnification obligations hereunder with respect to such settlement, compromise or judgment.

8. Contribution. In order to provide for contribution in circumstances in which the indemnification provided for in Section 7 is for any reason held to be unavailable from any indemnifying party or is insufficient to hold harmless a party indemnified thereunder, the Company and the Underwriters shall contribute to the aggregate losses, claims, damages, liabilities and expenses of the nature contemplated by such indemnification provision (including any investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claims asserted, but after deducting in the case of losses, claims, damages, liabilities and expenses suffered by the Company, any contribution received by the Company from Persons, other than the Underwriters, who may also be liable for contribution, including Persons who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, officers of the Company who signed the Registration Statement and directors of the Company) as incurred to which the Company and one or more of the Underwriters may be subject, in such proportions as is appropriate to

reflect the relative benefits received by the Company and the Underwriters from the Offering or, if such allocation is not permitted by applicable law, in such proportions as are appropriate to reflect not only the relative benefits referred to above but also the relative fault of the Company and the Underwriters in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company and the Underwriters shall be deemed to be in the same proportion as (x) the total proceeds from the Offering (net of underwriting discounts and commissions but before deducting expenses) received by the Company bears to (y) the underwriting discount or commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. The relative fault of each of the Company and of the Underwriters shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 8 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above in this Section 8 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any judicial, regulatory or other legal or governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this Section 8: (i) no Underwriter shall be required to contribute any amount in excess of the discounts and commissions applicable to the Securities underwritten by it and distributed to the public and (ii) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 8, each Person, if any, who controls an Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the

Exchange Act shall have the same rights to contribution as such Underwriter, and each Person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, each officer of the Company who shall have signed the Registration Statement and each director of the Company shall have the same rights to contribution as the Company, subject in each case to clauses (i) and (ii) of the immediately preceding sentence. Any party entitled to contribution will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim for contribution may be made against another party or parties, notify each party or parties from whom contribution may be sought, but the omission to so notify such party or parties shall not relieve the party or parties from whom contribution may be sought from any obligation it or they may have under this Section 8 or otherwise. The obligations of the Underwriters to contribute pursuant to this Section 8 are several in proportion to the respective number of Securities to be purchased by each of the Underwriters hereunder and not joint.

9. Underwriter Default.

(a) If any Underwriter or Underwriters shall default in its or their obligation to purchase Securities hereunder, and if the securities with respect to which such default relates (the "**Default Securities**") do not (after giving effect to arrangements, if any, made by the Representative pursuant to subsection (b) below) exceed in the aggregate 10% of the number of the Securities to be purchased on such date, each non-defaulting Underwriter, acting severally and not jointly, agrees to purchase from the Company that number of Default Securities that bears the same proportion of the total number of Default Securities then being purchased as the number of Firm Shares set forth opposite the name of such Underwriter on Schedule I hereto bears to the aggregate number of Firm Shares set forth opposite the names of the non-defaulting Underwriters, subject, however, to such adjustments to eliminate fractional shares as the Representative in its sole discretion shall make provided that the total number of Default Securities shall not be reduced by such adjustment.

(b) In the event that the aggregate number of Default Securities exceeds 10% of the number of the Securities to be purchased on such date, the Representative may in its discretion arrange for itself or for another party or parties (including any non-defaulting Underwriter or Underwriters who so agree) to purchase the Default Securities on the terms contained herein. In the event that within 48 hours after such a default the Representative does not arrange for the purchase of the Default Securities as provided in this Section 9, (i) this Agreement shall thereupon terminate if such Default Securities relate to the Firm Shares, without liability on the part of the Company with respect thereto (except in each case as provided in Sections 5, 7, 8 and 11(d)) or the Underwriters, but nothing in this Agreement shall relieve a defaulting Underwriter or Underwriters of its or their liability, if any, to the other Underwriters and the Company for damages occasioned by its or their default hereunder or (ii) with respect to any Option Closing Date which occurs after the Closing Date, the obligation of the Underwriters to purchase and of the Company to sell the Option Shares that were to have been purchased and sold on such Option Closing Date, shall terminate without liability on the part of any non defaulting Underwriter.

(c) In the event that any Default Securities are to be purchased by the non-defaulting Underwriters, or are to be purchased by another party or parties as aforesaid, the Representative or the Company shall have the right to postpone the Closing Date for a period, not exceeding five

(5) Business Days, in order to effect whatever changes may thereby be necessary in the Registration Statement or the Prospectus or in any other documents and arrangements, and the Company agrees to file promptly any amendment or supplement to the Registration Statement or the Prospectus which, in the reasonable opinion of Underwriters' Counsel, may thereby be made necessary or advisable. The term "Underwriter" as used in this Agreement shall include any party substituted under this Section 9 with like effect as if it had originally been a party to this Agreement with respect to such Firm Shares.

10. Survival of Representations and Agreements. All representations and warranties, covenants and agreements of the Company and the Underwriters contained in this Agreement or in certificates of officers of the Company submitted pursuant hereto, including the agreements contained in Sections 5, 10, 14 and 15, the indemnity agreements contained in Section 7 and the contribution agreements contained in Section 8 hereof, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of any Underwriter or any controlling Person thereof or by or on behalf of the Company, any of its officers and directors or any controlling Person thereof, and shall survive delivery of and payment for the Securities to and by the Underwriters. The covenants and agreements contained in Sections 5, 7, 8, this Section 10 and Sections 12, 13, 14 and 15 hereof shall survive any termination of this Agreement, including termination pursuant to Section 9 or 11 hereof. The representations and covenants contained in Sections 2, 3 and 4 hereof shall survive termination of this Agreement if any Securities are purchased pursuant to this Agreement.

11. Effective Date of Agreement; Termination.

(a) This Agreement shall become effective upon the later of: (i) receipt by the Representative and the Company of notification of the effectiveness of the Registration Statement or (ii) the execution of this Agreement.

(b) The Representative shall have the right to terminate this Agreement at any time prior to the consummation of the Closing if: (i) any domestic or international event or act or occurrence has materially disrupted the market for the Company's securities or securities in general in the United States; or (ii) trading generally on the New York Stock Exchange or the Nasdaq Stock Market shall have been wholly suspended or been made subject to material limitations, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required, on the New York Stock Exchange or the Nasdaq Stock Market or by order of the Commission, FINRA or any other governmental authority having jurisdiction; or (iii) a banking moratorium has been declared by any New York or federal authority or if any material disruption in commercial banking or securities settlement or clearance services shall have occurred; or (iv) (A) there shall have occurred any outbreak or escalation of hostilities or acts of terrorism involving the United States or there is a declaration of a national emergency or war by the United States or (B) there shall have been any other calamity or crisis or any change in political, financial or economic conditions if the effect of any such event in (A) or (B), in the reasonable judgment of the Representative, is so material and adverse and that such event makes it impracticable or inadvisable to proceed with the offering, sale and delivery of the Firm Shares on the terms and in the manner contemplated by the Prospectus.

(c) Any notice of termination pursuant to this Section 11 shall be in writing.

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(d) In the event this Agreement is terminated for any reason, the Representative shall contemporaneously terminate the agreements referred to in Section 4(k) entered into with the Lock-Up Parties.

If this Agreement shall be terminated pursuant to any of the provisions hereof or if the sale of the Securities provided for herein is not consummated because any condition to the obligations of the Underwriters set forth herein is not satisfied or because of any refusal, inability or failure on the part of the Company to perform any agreement herein or comply with any provision hereof, the Company will, subject to demand by the Representative, pay the out-of-pocket expenses actually incurred as allowed under FINRA Rule 5110 by the Underwriters through the date of such termination (including the Legal Cost Reimbursement) in an aggregate amount not to exceed \$100,000.

12. Notices. All communications hereunder, except as may be otherwise specifically provided herein, shall be in writing, and:

(a) if sent to the Representative or any Underwriter, shall be mailed, delivered, or faxed and confirmed in writing, to:

Maxim Group LLC  
405 Lexington Avenue  
New York, New York 10174  
Attention: Clifford A. Teller, Executive Managing Director of Investment Banking,  
Fax: 212-895-3555

with a copy to Underwriters' Counsel at:

Loeb & Loeb LLP  
345 Park Avenue  
New York, New York 10154  
Attention: Mitchell Nussbaum, Esq.  
Fax: 212-407-4990

(b) if sent to the Company, shall be mailed, delivered, or faxed and confirmed in writing to the Company and its counsel at the addresses set forth in the Registration Statement;

*provided, however,* that any notice to an Underwriter pursuant to Section 7 shall be delivered or sent by mail or facsimile transmission to such Underwriter at its address set forth in its acceptance facsimile to the Representative, which address will be supplied to any other party hereto by the Representative upon request. Any such notices and other communications shall take effect at the time of receipt thereof.

13. Parties; Limitation of Relationship. This Agreement shall inure solely to the benefit of, and shall be binding upon, the



Underwriters, the Company and the controlling Persons, directors, officers, employees and agents referred to in Sections 7 and 8 hereof, and their respective successors and assigns, and no other Person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are

intended to be for the sole and exclusive benefit of the parties hereto and said controlling Persons and their respective successors, officers, directors, heirs and legal representative, and it is not for the benefit of any other Person. The term “successors and assigns” shall not include a purchaser, in its capacity as such, of Securities from any of the Underwriters.

14. Submission of Jurisdiction; Governing Law:

1. This Agreement shall be governed by and construed in accordance with the laws of the State of New York. Each of the Company, the Representative and the Underwriters irrevocably (a) submits to the jurisdiction of any court of the State of New York for the purpose of any suit, action, or other proceeding arising out of this Agreement, or any of the agreements or transactions contemplated by this Agreement, the Registration Statement and the Prospectus (each, a “**Proceeding**”), (b) agrees that all claims in respect of any Proceeding may be heard and determined in any such court, (c) waives, to the fullest extent permitted by law, any immunity from jurisdiction of any such court or from any legal process therein, (d) agrees not to commence any Proceeding other than in such courts, and (e) waives, to the fullest extent permitted by law, any claim that such Proceeding is brought in an inconvenient forum. EACH OF THE COMPANY (ON BEHALF OF ITSELF AND, TO THE FULLEST EXTENT PERMITTED BY LAW, ON BEHALF OF ITS RESPECTIVE EQUITY HOLDERS AND CREDITORS), THE REPRESENTATIVE AND THE UNDERWRITERS HEREBY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY CLAIM BASED UPON, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, THE REGISTRATION STATEMENT, AND THE PROSPECTUS.

15. Entire Agreement. This Agreement, together with the exhibits, schedules and annexes attached hereto and as the same may be amended from time to time in accordance with the terms hereof, contains the entire agreement among the parties hereto relating to the subject matter hereof and there are no other or further agreements outstanding not specifically mentioned herein. For the avoidance of doubt, this Agreement shall supersede the terms of that certain Engagement Letter, dated September , 2015 entered into by and between the Company and the Representative and such engagement letter shall have no further force or effect from and after the date of this Agreement.

16. Severability. If any term or provision of this Agreement or the performance thereof shall be invalid or unenforceable to any extent, such invalidity or unenforceability shall not affect or render invalid or unenforceable any other provision of this Agreement and this Agreement shall be valid and enforced to the fullest extent permitted by law.

17. Amendment. This Agreement may only be amended by a written instrument executed by each of the parties hereto.

18. Waiver, etc. The failure of any of the parties hereto to at any time enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way effect the validity of this Agreement or any provision hereof or the right of any of the parties hereto to thereafter enforce each and every provision of this Agreement. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions

of this Agreement shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

19. No Fiduciary Relationship. The Company hereby acknowledges that the Underwriters are acting solely as underwriters in connection with the offering of the Company’s Securities. The Company further acknowledge that the Underwriters are acting pursuant to a contractual relationship created solely by this Agreement entered into on an arm’s length basis and in no event do the parties intend that the Underwriters act or be responsible as a fiduciary to the Company, its management, shareholders, creditors or any other person in connection with any activity that the Underwriters may undertake or have undertaken in furtherance of the offering of the Company’s Securities, either before or after the date hereof. The Underwriters hereby expressly disclaim any fiduciary or similar obligations to the Company, either in connection with the transactions contemplated by this Agreement or any matters leading up to such transactions, and the Company hereby confirms its understanding and agreement to that effect. The Company hereby further confirms its understanding that no Underwriter has assumed an advisory or fiduciary responsibility in favor of the Company with respect to the Offering contemplated hereby or the process leading thereto, including any negotiation related to the pricing of the Securities; and the Company has consulted its own legal and financial advisors to the extent it has deemed appropriate in connection with this Agreement and the Offering. The Company and the Underwriters agree that they are each responsible for making their own independent judgments with respect to any such transactions, and that any opinions or views expressed by the Underwriters to the Company regarding such transactions, including but not limited to any opinions or views with respect to the price or market for the Company’s securities, do not constitute advice or recommendations to the Company. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any breach or alleged breach of any fiduciary or similar duty to the Company in connection with the transactions contemplated by this Agreement or any matters leading up to such transactions.

20. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same instrument. Delivery of a signed counterpart of this Agreement by facsimile or other electronic transmission shall constitute valid and sufficient delivery thereof.

21. Headings. The headings herein are inserted for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

22. Time is of the Essence. Time shall be of the essence of this Agreement. As used herein, the term "Business Day" shall mean any day other than a Saturday, Sunday or any day on which the major stock exchanges in New York, New York are not open for business.

[Signature Pages Follow]

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If the foregoing correctly sets forth your understanding, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among us.

Very truly yours,

CERECOR INC.

By: \_\_\_\_\_

Name: Blake M. Paterson

Title: President and Chief Executive Officer

**Accepted by the Representative, acting for themselves and as Representative of the Underwriters named on Schedule I attached hereto, as of the date first written above:**

MAXIM GROUP LLC

By: \_\_\_\_\_

Name: Clifford A. Teller

Title: Executive Managing Director, Investment Banking

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**CERECOR INC.**

**SCHEDULE I**

**Name of  
Underwriter**

**Number of Firm Shares Being Purchased**

Maxim Group LLC

Laidlaw & Company (UK) Ltd.

**SCHEDULE II**

**Free Writing Prospectus**

**SCHEDULE III**

**Lock-Up Parties**

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**ANNEX IV**

**Form of Representative's Warrant**

NEITHER THESE SECURITIES NOR THE SECURITIES ISSUABLE UPON EXERCISE OF THESE SECURITIES HAVE BEEN

REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY. THESE SECURITIES AND THE SECURITIES ISSUABLE UPON EXERCISE OF THESE SECURITIES MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT SECURED BY SUCH SECURITIES.

**CERECOR INC.**

**COMMON STOCK WARRANT**

Warrant No. [ ]

Original Issue Date: , 2015

Cerecor Inc., a Delaware corporation (the “**Company**”), hereby certifies that, as partial compensation for its services as underwriter to the Company, or its registered assigns (the “**Holder**”), is entitled to at any time and from time to time commencing on [ , 2015], the effective date of the Registration Statement (the “**Effective Date**”), through and including [ , 2020], the fifth anniversary of the Effective Date (the “**Expiration Date**”), but not thereafter, exercise this Warrant to purchase and receive in whole or in part up to [ ](2)shares of common stock, par value \$0.001 per share of the Company (the “**Common Stock**”) underlying this Warrant (the “**Warrant Shares**”), subject to the following terms and conditions:

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(2) Amount to equal 1% of the Firm Shares sold in the Offering; provided, however, if more than one warrant is issued, the aggregate amount of shares underlying all of the warrants will equal 1% of the Firm Shares sold in the Offering.

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1. Definitions. As used in this Warrant, the following terms shall have the respective definitions set forth in this Section 1.

“**Affiliate**” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 144.

“**Business Day**” means any day except Saturday, Sunday and any day which is a federal legal holiday or a day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

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

“**Exercise Price**” means \$[ ] per share(3) , subject to adjustment in accordance with Section 10.

“**Fundamental Transaction**” means any of the following: (1) the Company effects any merger or consolidation of the Company with or into another Person, (2) the Company effects any sale of all or substantially all of its assets in one or a series of related transactions, (3) any tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to tender or exchange their shares for other securities, cash or property, (4) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property or (5) the Company authorizes the voluntary dissolution, liquidation or winding up of affairs of the Company.

“**New York Courts**” means the state and federal courts sitting in the City of New York, Borough of Manhattan.

“**Offering**” has the meaning as set forth in that certain Underwriting Agreement, dated as of [ ], 2015, by and between the Company and Maxim Group LLC, as the representative of the Underwriters named on Schedule I thereto.

“**Original Issue Date**” means the Original Issue Date first set forth on the first page of this Warrant.

“**Person**” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“**Prospectus**” means the prospectus dated [ , 2015] filed with the Securities and Exchange Commission pursuant to Rule 424(b) promulgated under the Securities Act.

“**Rule 144**” means Rule 144 promulgated by the Securities and Exchange Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar

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(3) Exercise price will equal 115% of the price of the Firm Shares sold in the Offering.

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rule or regulation hereafter adopted by the Securities and Exchange Commission having substantially the same effect as such Rule.

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

“**Subsidiary**” means any “significant subsidiary” as defined in Rule 1-02(w) of Regulation S-X promulgated by the Securities and Exchange Commission under the Exchange Act.

“**Trading Day**” means (i) a day on which the Common Stock is traded on a Trading Market, or (ii) if the Common Stock is not quoted on any Trading Market, a day on which the Common Stock is quoted in the over-the-counter market as reported by OTC Markets Group Inc. (or any similar organization or agency succeeding to its functions of reporting prices); provided, that in the event that the Common Stock is not listed or quoted as set forth in (i) or (ii) hereof, then Trading Day shall mean a Business Day.

“**Trading Market**” means whichever of the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Select Market, the NASDAQ Global Market, the NASDAQ Capital Market or the OTC Bulletin Board on which the Common Stock is listed or quoted for trading on the date in question.

2. Registration of Warrant. The Company shall register this Warrant upon records to be maintained by the Company for that purpose (the “**Warrant Register**”), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. General Restrictions on Transfers. The registered Holder of this Warrant agrees by his, her or its acceptance hereof, that except by operation of law or by reason of reorganization of the Company, such Holder will not: (a) sell, transfer, assign, pledge or hypothecate this Warrant for a period of one hundred eighty (180) days following the Effective Date to any person other than to (i) Maxim Group LLC (“**Maxim**”) or an underwriter or a selected dealer participating in the Offering, or (ii) an officer or partner of Maxim or of any such underwriter or selected dealer, and in each case the Warrant so transferred must remain subject to the foregoing lock-up restriction for the remainder of the time period in accordance with FINRA Conduct Rule 5110(g)(1), or (b) cause this Warrant or the Warrant Shares issuable hereunder to be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of this Warrant or the Warrant Shares hereunder, other than the transfer to (i) Maxim or an underwriter or a selected dealer participating in the Offering, or (ii) an officer or partner of Maxim or of any such underwriter or selected dealer, and in each case the Warrant so transferred must remain subject to the foregoing lock-up restriction for the remainder of the time period in accordance with FINRA Conduct Rule 5110(g)(1). On and after 180 days after the Effective Date, transfers to others may be made subject to compliance with or exemptions from applicable securities laws. In order to make any permitted assignment, the Holder must deliver to the Company the assignment form attached hereto duly executed and completed, together with the Warrant and payment of all transfer taxes, if any, payable in connection therewith. The Company shall within five (5) Business Days transfer this Warrant on

the books of the Company and shall execute and deliver a new Warrant or Warrants of like tenor to the appropriate assignee(s) expressly evidencing the right to purchase the aggregate number of Warrant Shares purchasable hereunder or such portion of such number as shall be contemplated by any such assignment.

4. Restrictions Imposed by the Securities Act. The securities evidenced by this Warrant shall not be transferred unless and until: (i) the Company has received the opinion of counsel for the Holder that the securities may be transferred pursuant to an exemption from registration under the Securities Act and applicable state securities laws, the availability of which is established to the reasonable satisfaction of the Company (the Company hereby agreeing that the opinion of Loeb & Loeb LLP that the securities may be transferred pursuant to an exemption from registration under the Securities Act and applicable state securities laws shall be deemed satisfactory evidence of the availability of an exemption), or (ii) a registration statement relating to the offer and sale of such securities has been filed by the Company and declared effective by the U.S. Securities and Exchange Commission (the “**Commission**”) and compliance with applicable state securities law has been established.

5. Exercise and Duration of Warrants. This Warrant shall be exercisable by the registered Holder at any time and from time to time commencing on Effective Date, through and including the Expiration Date. At 6:30 p.m., New York City time on the Expiration Date, the portion of this Warrant not exercised prior thereto shall be and become void and of no value. The Company may not call or redeem any portion of this Warrant without the prior written consent of the affected Holder.

6. Delivery of Warrant Shares.

(a) Upon delivery of the Exercise Notice (in the form attached hereto) to the Company (with the attached Warrant Exercise Log) at its address for notice set forth herein and upon payment of the Exercise Price multiplied by the number of Warrant Shares that the Holder intends to purchase hereunder, the Company shall promptly (but in no event later than five (5) Trading Days after the Date of Exercise (as defined herein)) issue and deliver to the Holder, a certificate for the Warrant Shares issuable upon such exercise.

(b) Each certificate for the Warrant Shares purchased under this Warrant shall bear a legend as follows unless such securities have been registered under the Securities Act:

“The securities represented by this certificate have not been registered under the Securities Act of 1933, as amended (the “**Act**”),

or applicable state law. Neither the securities nor any interest therein may be offered for sale, sold or otherwise transferred except pursuant to an effective registration statement under the Securities Act, or pursuant to an exemption from registration under the Securities Act and applicable state law which, in the opinion of counsel to the Company, is available.”

(c) The Company shall, upon request of the Holder and subsequent to the date on which a registration statement covering the resale of the Warrant Shares has been declared effective by the Commission, use its commercially reasonable efforts to deliver Warrant Shares

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hereunder electronically through the Depository Trust Corporation or another established clearing corporation performing similar functions, if available, provided, that, the Company may, but will not be required to change its transfer agent if its current transfer agent cannot deliver Warrant Shares electronically through the Depository Trust Corporation. A “**Date of Exercise**” means the date on which the Holder shall have delivered to the Company: (i) the Exercise Notice (with the Warrant Exercise Log attached to it), appropriately completed and duly signed and (ii) payment of the Exercise Price for the number of Warrant Shares so indicated by the Holder to be purchased.

(d) If by the fifth Trading Day after a Date of Exercise the Company fails to deliver the required number of Warrant Shares in the manner required pursuant to Section 6(a), then the Holder will have the right to rescind such exercise.

(e) If by the fifth Trading Day after a Date of Exercise the Company fails to deliver the required number of Warrant Shares in the manner required pursuant to Section 6(a), and if after such fifth Trading Day and prior to the receipt of such Warrant Shares, the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a “**Buy-In**”), then the Company shall (1) pay in cash to the Holder the amount by which (x) the Holder’s total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (such number of shares not to exceed the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise) exceeds (y) the amount obtained by multiplying (A) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue by (B) the closing bid price of the Common Stock on the Date of Exercise and (2) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored or deliver to the Holder the number of shares of Common Stock or Warrants that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In, and, upon request of the Company, evidence of the amount of such loss.

(f) The Company’s obligations to issue and deliver Warrant Shares in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance which might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Warrant Shares. Nothing herein shall limit a Holder’s right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company’s failure to timely deliver certificates representing Warrant Shares upon exercise of the Warrant as required pursuant to the terms hereof.

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7. Charges, Taxes and Expenses. Issuance and delivery of Warrant Shares upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, withholding tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; provided, however, that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the registration of any certificates for Warrant Shares or Warrants in a name other than that of the Holder. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

8. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a new warrant, (a “**New Warrant**”), but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction and customary and reasonable indemnity (which shall not include a surety bond), if requested. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company’s obligation to issue the New Warrant.

9. Reservation of Warrant Shares. The Company covenants that it will at all times reserve and keep available shares of Common Stock solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of shares of Common Stock which are then issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of Persons other than the Holder (taking into account the adjustments and restrictions of Section 10). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable.

10. Certain Adjustments. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 10.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock, (ii) subdivides outstanding shares of Common Stock into a larger number of shares, or (iii) combines outstanding shares of Common Stock into a smaller number of shares, then in each such case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

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(b) Fundamental Transactions. If, at any time while this Warrant is outstanding there is a Fundamental Transaction, then the Holder shall have the right thereafter to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant (the “**Alternate Consideration**”). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. At the Holder’s option and request, any successor to the Company or surviving entity in such Fundamental Transaction shall issue to the Holder a new warrant substantially in the form of this Warrant and consistent with the foregoing provisions and evidencing the Holder’s right to purchase the Alternate Consideration for the aggregate Exercise Price upon exercise thereof. The terms of any agreement pursuant to which a Fundamental Transaction is effected shall include terms requiring any such successor or surviving entity to comply with the provisions of this paragraph (b) and insuring that the Warrant (or any such replacement security) will be similarly adjusted upon any subsequent transaction analogous to a Fundamental Transaction.

(c) Adjustments for Other Distributions. In the event the Company shall declare a distribution on the outstanding Common Stock that is payable in securities of other Persons, evidences of indebtedness issued by the Company or other Persons, assets (excluding cash dividends or distributions to the holders of Common Stock paid out of current or retained earnings and declared by the Company’s board of directors) or options or rights, then, in each such case for the purpose of this Section 10(c), upon exercise of this Warrant, the Holder shall be entitled to a proportionate share of any such distribution as though the Holder was the actual record holder of the number of shares of Common Stock which might have been purchased upon exercise of this Warrant immediately prior to the record date fixed for the determination of the holders of Common Stock of the Company entitled to receive such distribution (or the date of such distribution if no record date is fixed).

(d) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to this Section 10, the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the adjusted number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Calculations. All calculations under this Section 10 shall be made to the nearest cent or the nearest whole share, as applicable. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the

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Company, and the disposition of any such shares shall be considered outstanding shares of Common Stock.

Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 10, the Company at its expense will promptly compute such adjustment in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company’s transfer agent.

11. Payment of Exercise Price. The Holder may pay the Exercise Price in one of the following manners:

(a) Cash Exercise. The Holder may deliver immediately available funds; or

(b) Cashless Exercise. If on the Date of Exercise there is no effective registration statement registering, or the prospectus contained therein is not available for, the resale of the Warrant Shares, the Holder may notify the Company in an Exercise Notice of its election to utilize cashless exercise, in which event the Company shall issue to the Holder the number of Warrant Shares

determined as follows:

$$X = Y [(A-B)/A]$$

where:

X = the number of Warrant Shares to be issued to the Holder.

Y = the number of Warrant Shares with respect to which this Warrant is being exercised.

A = the fair market value of one share of Common Stock.

B = the Exercise Price.

For purposes of this Section 11(b), the fair market value of one share of Common Stock is defined as follows:

(i) if the Company's Common Stock is traded on a Trading Market, the fair market value shall be deemed the closing price on such Trading Market on the Trading Day immediately prior to the date the exercise form is submitted to the Company in connection with the exercise of this Warrant; or

(ii) if the Company's Common Stock is actively traded over-the-counter, the fair market value shall be deemed to be the closing bid on the Trading Day immediately

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prior to the date the exercise form is submitted in connection with the exercise of this Warrant; or

(iii) if there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Company's board of directors.

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Warrant Shares issued in a cashless exercise transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued.

12. No Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares which would, otherwise be issuable, the Company shall pay cash equal to the product of such fraction multiplied by the closing price of one Warrant Share as reported by the applicable Trading Market on the date of exercise.

13. Registration Rights.

(a) Demand Registration. The Company, upon written demand (a "**Demand Notice**") of the Holder(s) of at least 51% of the underlying Warrant Shares ("**Majority Holders**"), agrees to register (a "**Demand Registration**"), on no more than two occasions, all or any portion of the Warrant Shares underlying this Warrant (collectively the "**Registrable Securities**") so long as such registration is with respect to at least thirty-three percent (33%) of the Registrable Securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed \$5 million). For the avoidance of doubt, in the event that more than one warrant is issued as compensation to an underwriter of the Company in the Offering, a Demand Registration may be made only upon written demand of the Holders of at least 51% of the total outstanding Warrant Shares underlying all outstanding warrants. On such occasion, the Company will file a registration statement covering the Registrable Securities within sixty (60) days after receipt of a Demand Notice and use its commercially reasonable efforts to have such registration statement declared effective promptly thereafter, subject to compliance with review by the Commission; provided, however, that the Company shall not be required to comply with a Demand Notice if the Company has filed a registration statement or in the Company's good faith estimate it plans to file a registration statement within sixty (60) days following such demand with respect to which the Holder is entitled to piggy-back registration rights pursuant to Section 13(b) hereof and either: (i) the Holder was or will be given the opportunity to exercise its piggy-back registration rights with respect to all of the underlying Warrant Shares under Section 13(b) hereof in connection with the offering covered by such registration statement or (ii) if such registration statement relates to an underwritten primary offering of securities of the Company, until the offering covered by such registration statement has been withdrawn or until thirty (30) days after such offering is consummated; provided further that the Company may be permitted to defer taking action with respect to filing a registration statement for a period of not more than ninety (90) days after the date of the Demand Notice if the Company's board of directors determines in its good faith judgment that it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such

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registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act.

The Company covenants and agrees to give written notice of its receipt of any Demand Notice by any Holder(s) to all other registered Holders of the Warrants issued in connection with the Offering and/or the Warrant Shares thereunder within ten (10) days from the date of the receipt of such Demand Notice. The Holders of Warrants issued in connection with the Offering shall not, in the aggregate, effect more than two (2) Demand Registrations pursuant to this Section 13(a). A registration will not count as a Demand Registration until the registration statement filed with the Commission with respect to such Demand Registration has been declared effective and the Company has complied with all of its obligations hereunder with respect thereto unless the Majority Holders withdraw their request for such registration and elect not to pay the registration expenses therefor that were incurred by the Company; provided, however, that if, after such registration statement has been declared effective, the offering of Registrable Securities pursuant to a Demand Registration is interfered with by any stop order or injunction of the Commission or any other governmental agency or court, the registration statement with respect to such Demand Registration will be deemed not to have been declared effective, unless and until, (i) such stop order or injunction is removed, rescinded or otherwise terminated, and (ii) the Majority Holders thereafter elect to continue the offering. The Company shall bear all fees and expenses attendant to the first Demand Registration pursuant to Section 13(a), including the reasonable and documented expenses of a single legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities in an amount not to exceed \$50,000, but the Holders shall pay any and all underwriting commissions or brokerage fees related to the Registrable Securities, if applicable. The fees and expenses attendant to an additional Demand Registration pursuant to this Section 13(a) shall be borne by the Holder(s). The Company agrees to use its commercially reasonable efforts to cause the filing required herein to become effective promptly. The Company shall use its commercially reasonable efforts to cause any registration statement filed pursuant to a Demand Registration to remain effective for a period of at least six (6) consecutive months from the effective date of such registration statement or, if earlier, until the distribution contemplated in the registration statement has been completed. The Holders shall only use the prospectuses provided by the Company to sell the shares covered by such registration statements, and will immediately cease to use any prospectus furnished by the Company if the Company advises the Holder that such prospectus may no longer be used due to a material misstatement or omission.

(b) “Piggy-Back” Registration. In addition to the Demand Registration described in Section 13(a) hereof, the Holder shall have the right to include the Registrable Securities as part of any other registration of securities filed by the Company solely for cash (other than (I) in connection with a transaction contemplated by Rule 145(a) promulgated under the Securities Act, (II) pursuant to Form S-8 or any equivalent form, or (III) a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered) (the **“Piggy-Back Registration”**). The Holders shall be entitled to unlimited piggy-back registration rights pursuant to this Section 13(b). The

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Company shall use its commercially reasonable efforts to cause such Registrable Securities to be included in such registration statement and shall use its commercially reasonable efforts to cause the managing underwriter(s) of a proposed underwritten offering to permit the Registrable Securities requested to be included in a Piggy-Back Registration on the same terms and conditions as any similar securities of the company and to permit the sale or other disposition of such Registrable Securities in accordance with the intended method(s) of distribution thereof, unless, in the reasonable business judgment of the Company and the managing underwriter(s), the inclusion of the Registrable Securities in the registration statement would materially impair the Company’s or the selling stockholder’s ability to sell all of the shares otherwise included in such registration statement. Then the Company shall be obligated to include in such registration statement only such limited portion of the Registrable Securities with respect to which the Holder requested inclusion hereunder as the managing underwriter(s) shall reasonably permit. Any exclusion of Registrable Securities shall be made pro rata among the Holders seeking to include Registrable Securities in proportion to the number of Registrable Securities sought to be included by such Holders; provided, however, that the Company shall not exclude any Registrable Securities unless the Company has first excluded all outstanding securities, the holders of which are not entitled to inclusion of such securities in such registration statement or are not entitled to pro rata inclusion with the Registrable Securities. Any Holder of Registrable Securities may elect to withdraw such Holder’s request for inclusion of Registrable Securities in any Piggy-Back Registration by giving written notice to the Company of such request to withdraw prior to the effectiveness of the registration statement. The Company (whether on its own determination or as the result of a withdrawal by persons making a demand pursuant to written contractual obligations) may withdraw a registration statement at any time prior to the effectiveness of the registration statement. Notwithstanding any such withdrawal, the Company shall pay all expenses incurred by the Holders of Registrable Securities in connection with such Piggy-Back Registration as provided in this Section 13(b). The Company shall bear all fees and expenses attendant to registering the Registrable Securities pursuant to this Section 13(b), including the reasonable and documented expenses of a single legal counsel selected by the Holder(s) to represent them in connection with the sale of the Registrable Securities, but the Holder(s) shall pay any and all underwriting commissions or brokerage fees related to the Registrable Securities. In the event of such a proposed registration, the Company shall furnish the then Holder(s) of outstanding Registrable Securities with not less than ten (10) days written notice prior to the proposed date of filing of such registration statement. Such notice to the Holder(s) shall continue to be given for each registration statement filed by the Company until such time as all of the Registrable Securities have been sold by the Holder(s). The Holder(s) of the Registrable Securities shall exercise the “piggy-back” rights provided for herein by giving written notice, within five (5) days of the receipt of the Company’s notice of its intention to file a registration statement. All Holder(s) proposing to distribute their Registrable Securities through a Piggy-Back Registration that involves an underwriter or underwriters shall enter into an underwriting agreement in customary form with the underwriter(s) selected for such Piggy-Back Registration.

(c) It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 13 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder’s Registrable Securities.

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(d) The rights set forth in this Section 13 shall terminate upon the earliest to occur of (i) the fifth anniversary of the Effective Date and (ii) when all Registrable Securities may be sold without restriction under Rule 144 promulgated by the Commission under the Securities Act.

14. No Rights as Stockholder. This Warrant does not entitle the Holder to any of the rights of a stockholder of the Company, including, without limitation, except as otherwise set forth herein, the right to receive dividends, or other distributions, exercise any preemptive rights to vote or to consent or to receive notice as stockholders in respect of the meetings of stockholders or the election of directors of the Company or any other matter.

15. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in this Section 15 prior to 6:30 p.m. (New York City time) on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in this Section 15 on a day that is not a Trading Day or later than 6:30 p.m. (New York City time) on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. The addresses for such communications shall be: (i) if to the Company, to Cerecor Inc., 400 East Pratt St., Suite 606, Baltimore, MD 21202, facsimile number: 410-327-4084, Attention: Chief Executive Officer (or such other address as the Company shall indicate in writing in accordance with this Section 15), or (ii) if to the Holder, to the address or facsimile number appearing on the Warrant Register or such other address or facsimile number as the Holder may provide to the Company in accordance with this Section 15.

16. Miscellaneous.

(a) This Warrant shall be binding on and inure to the benefit of the parties hereto and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder and their successors and assigns.

(b) All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of this Warrant and the transactions herein contemplated ("**Proceedings**") (whether brought against a party hereto or its respective Affiliates, employees or agents) shall be commenced exclusively in the New York Courts. Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any Proceeding, any claim that it is not personally subject to the jurisdiction of any New York Court, or that such

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Proceeding has been commenced in an improper or inconvenient forum. Each party hereto hereby irrevocably waives personal service of process and consents to process being served in any such Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Warrant or the transactions contemplated hereby. If either party shall commence a Proceeding to enforce any provisions of this Warrant, then the prevailing party in such Proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Proceeding.

(c) The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(d) In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby and the parties will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

(e) Prior to exercise of this Warrant, the Holder hereof shall not, by reason of being a Holder, be entitled to any rights of a stockholder with respect to the Warrant Shares.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK,  
SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its authorized officer as of the date first indicated above.

CERECOR INC.

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

EXERCISE NOTICE  
CERECOR INC.  
WARRANT DATED \_\_\_\_\_, 2015

The undersigned Holder hereby irrevocably elects to purchase \_\_\_\_\_ Warrant Shares pursuant to the above referenced Warrant. Capitalized terms used herein and not otherwise defined have the respective meanings set forth in the Warrant.

- (1) The undersigned Holder hereby exercises its right to purchase \_\_\_\_\_ Warrant Shares pursuant to the Warrant.
- (2) (PLEASE CHECK ONE METHOD OF PAYMENT) The Holder shall pay the sum of \$ \_\_\_\_\_ to the Company in accordance with the terms of the Warrant OR The Holder shall exercise the Warrant cashlessly in accordance with the terms of the Warrant.
- (3) Pursuant to this Exercise Notice, the Company shall deliver to the holder \_\_\_\_\_ Warrant Shares in accordance with the terms of the Warrant.

Dated: \_\_\_\_\_, \_\_\_\_\_ Name of Holder: \_\_\_\_\_  
 (Print) \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

(Signature must conform in all respects to name of holder as specified on the face of the Warrant)

Warrant Exercise Log

<b>Date</b>	<b>Number of Warrant Shares Available to be Exercised</b>	<b>Number of Warrant Shares Exercised</b>	<b>Number of Warrant Shares Remaining to be Exercised</b>

CERECOR INC.  
WARRANT DATED \_\_\_\_\_, 2015  
WARRANT NO. [ ]

FORM OF ASSIGNMENT

[To be completed and signed only upon transfer of Warrant]

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers unto \_\_\_\_\_ the right represented by the above-captioned Warrant to purchase \_\_\_\_\_ share of Company Common Stock and appoints \_\_\_\_\_ attorney to transfer said right on the books of the Company with full power of substitution in the premises.

Dated: \_\_\_\_\_, \_\_\_\_\_

\_\_\_\_\_  
(Signature must conform in all respects to name of holder as

specified on the face of the Warrant)

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Address of Transferee

In the presence of:

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated April 29, 2015 (except for the third and fourth paragraph of Note 14, as to which the date is September 4, 2015), in Amendment No. 2 to the Registration Statement (Form S-1 No. 333-204905) and related Prospectus of Cerecor Inc. for the registration of its Common Stock.

/s/ Ernst & Young LLP

Baltimore, Maryland  
September 21, 2015

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