Filed Pursuant to Rule 424(b)(3)
Registration No. 333-204905

Prospectus Supplement No. 12
(To Prospectus dated October 14, 2015)

4,000,000 shares of common stock issuable upon the exercise of the 4,000,000 outstanding Class A warrants

and

2,000,000 shares of common stock issuable upon the exercise of the 4,000,000 outstanding Class B warrants

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This prospectus supplement No. 12 supplements the prospectus dated October 14, 2015 filed pursuant to Rule 424(b)(4) by Cerecor Inc. (the "Company" or "we"), as supplemented by the prospectus supplement No. 1 dated October 20, 2015, the prospectus supplement No. 2 dated November 13, 2015, the prospectus supplement No. 3 dated November 23, 2015, the prospectus supplement No. 4 dated December 17, 2015, the prospectus supplement No. 5 dated December 21, 2015, the prospectus supplement No. 6 dated December 29, 2015, the prospectus supplement No. 7 dated January 5, 2016, the prospectus supplement No. 8 dated January 12, 2016, the prospectus supplement No. 9 dated January 19, 2016, the prospectus supplement No. 10 dated February 2, 2016 and the prospectus supplement No. 11 dated April 11, 2016, each filed pursuant to Rule 424(b)(3) by the Company (collectively, the "Prospectus"). Pursuant to the Prospectus, this prospectus supplement relates to the continuous offering of 4,000,000 shares of common stock underlying our Class A warrants and 2,000,000 shares of our common stock underlying Class B warrants. Each warrant was a component of a unit that we issued in our initial public offering, which closed on October 20, 2015. The components of the units began to trade separately on November 13, 2015. Each Class A warrant became exercisable on the date when the units detached and the components began to trade separately and will expire on October 20, 2018, or earlier upon redemption. Each Class B warrant became exercisable on the date the units detached and the components began to trade separately and will expire on April 20, 2017.

This prospectus supplement incorporates into our Prospectus the information contained in our attached Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 23, 2016.

You should read this prospectus supplement in conjunction with the Prospectus, including any supplements and amendments thereto. This prospectus supplement is qualified by reference to the Prospectus except to the extent that the information in this prospectus supplement supersedes the information contained in the Prospectus.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any supplements and amendments thereto.

Our common stock, the Class A warrants and the Class B warrants are traded on The NASDAQ Capital Market under the symbols "CERC," "CERCW," and "CERCZ," respectively.

AN INVESTMENT IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE THE SECTION ENTITLED "RISK FACTORS" BEGINNING ON PAGE 16 OF THE PROSPECTUS FOR A DISCUSSION OF INFORMATION THAT SHOULD BE CAREFULLY CONSIDERED IN CONNECTION WITH AN INVESTMENT IN OUR SECURITIES

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 date of this prospectus supplement is May 25, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

OR

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

Commission File No. 001-37590

Cerecor Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-0705648**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

400 E. Pratt Street, Suite 606
Baltimore, Maryland 21202
(Address of principal executive offices)

Telephone: (410) 522-8707
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001, par value Class A Warrants, consisting of the right to purchase one share of common stock at an exercise price of $4.55 per share Class B Warrants, consisting of the right to purchase one-half share of common stock at an exercise price of $3.90 per share	NASDAQ Stock Market

Securities registered pursuant to section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§299.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

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

As of March 16, 2016, there were 8,650,143 outstanding shares of the registrant's common stock, par value $0.001 per share. There was no aggregate market value of shares of common stock held by non-affiliates of the registrant as of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, because the registrant's common stock was not trading on any exchange on that date.

Documents Incorporated by Reference: Portions of the registrant's Definitive Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year ended December 31, 2015, are incorporated by reference in Part III of this Annual Report on Form 10-K.

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PART I

FORWARD-LOOKING STATEMENTS

This report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as “believes,” “expects,” “may,” “will,” “plans,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “aims,” “projects,” “predicts,” “pro forma,” “anticipates,” “potential” or other similar words (including their use in the negative), or by discussions of future matters such as the development of product candidates or products, technology enhancements, possible changes in legislation, and other statements that are not historical. These statements include but are not limited to statements under the captions “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the caption “Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and cause our results to differ materially from those expressed or implied by our forward-looking statements. If any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report.

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company that is developing innovative drug candidates to make a difference in the lives of patients with neurological and psychiatric disorders. We have a portfolio of novel clinical and preclinical compounds that we are developing for a variety of indications:

- ***CERC-301: Adjunctive Treatment for Major Depressive Disorder.*** 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 has the potential to produce a significant reduction in depression symptoms in a matter of days, as compared to weeks or months with conventional therapies, because it specifically blocks the NMDA receptor subunit 2B, or NR2B. We believe this mechanism of action may provide rapid and significant antidepressant activity without the adverse side effect profile of non-selective NMDA receptor antagonists. Provided we are able to demonstrate efficacy and continued safety in our Phase 2 trial we plan to move forward with Phase 3 development. We may also consider initiating separate development programs in other indications, such as active suicidal ideation.

- ***CERC-501: Substance Use Disorders and Adjunctive Treatment for MDD.*** CERC-501 is currently in Phase 2 development for smoking cessation. CERC-501 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 intend to develop CERC-501 for adjunctive treatment of MDD and for substance use disorders (e.g., nicotine, alcohol, and/or cocaine) and have initiated a Phase 2 proof of concept clinical trial in smoking cessation. In addition, two external clinical trials are being conducted evaluating the use of CERC-501 in treating cocaine addiction and mood disorders. One study is being conducted under the auspices of the National Institute of Mental Health, or NIMH, and a second study is being funded by a private foundation. Provided that the outcome of our smoking cessation trial is positive, we plan to conduct a Phase 2 dose-ranging trial in smokers. We are also planning to conduct a Phase 2 trial in inadequately treated patients with MDD.
- ***CERC-406: Cognitive Impairment.*** CERC-406 is our lead preclinical 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 believe CERC-406 has potential as a 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 Abilify®, BuSpar®, Cymbalta®, Nuplazid™, Prozac®, Serzone® and Zyprexa®. Collectively, our officers and directors have contributed to the submission of numerous Investigational New Drug Applications, or INDs, and New Drug Applications, or NDAs, to the FDA.

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 potential product candidates, ideally those 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 current treatments fail to address unmet medical needs, and where we believe we can apply clinical strategies to increase efficacy signal detection with a view to optimizing the clinical development and regulatory pathway for our product candidates. These strategies include using personalized therapeutic approaches and placebo mitigation techniques.

Our strategic objectives include:

- ***Develop and commercialize our lead clinical product candidates, CERC-301 and CERC-501.***

  CERC-301: We have initiated a Phase 2 efficacy trial for CERC-301 in order to evaluate the effect of intermittent oral doses of 12 mg and 20 mg versus placebo. If we are successful in demonstrating efficacy and continued safety in this trial we anticipate moving forward with Phase 3 development. We may consider initiating separate development programs in other indications, such as active suicidal ideation.

  CERC-501: We have initiated a Phase 2 proof of concept clinical trial in smoking cessation, which will provide us with the opportunity to evaluate the effect of 15 mg of CERC-501 administered orally once per day on tobacco reinstatement behavior and assess subjects' craving, mood and anxiety during abstinence periods. There are two additional external trials being conducted evaluating the use of CERC-501 in treating cocaine addiction and mood disorders. One study is being conducted under the auspices of NIMH and a second study is being funded by a private foundation. Provided that the outcome of our smoking cessation trial is positive, we plan to conduct a Phase 2 dose-ranging trial in smokers. We are also planning to conduct a Phase 2 trial in inadequately treated patients with MDD.

- ***Leverage the commercial potential of CERC-301 and CERC-501 by expanding to additional neurological and psychiatric disorders.*** Many major pharmaceutical companies have deemphasized their neuroscience discovery and development programs in recent years. Given our focus and expertise in developing treatments for neurological and psychiatric disorders, these programs represent compelling opportunities for us. 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. Additionally, collaborations, through licenses or strategic partnerships, may provide access to the considerable scientific, development, regulatory and commercial capabilities of larger biopharmaceutical corporations, potentially providing us with additional infrastructure to more efficiently develop and commercialize assets in our product candidate portfolio.

- ***Pursue non-dilutive financing arrangements to fund future development.*** We will evaluate opportunities to fund the future development of our clinical and preclinical product candidates, as well as our goal of expansion to additional neurological and psychiatric disorders, via non-dilutive financing arrangements such as government funding and through other collaboration arrangements with strategic partners.

- ***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.

- ***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, we believe we have the potential to address the impairment of executive function in a highly specific manner, guided by biomarkers and pharmacogenomics. We anticipate advancing CERC-406 into preclinical IND-enabling studies and may 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-stage development collaborations with third parties on an indication-specific basis in order to maximize the value of our COMTi platform.

Product Pipeline

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

Product Candidate / Platform	Potential Indication(s)	Stage of Development	Anticipated Milestones
CERC-301	Adjunctive treatment of MDD with rapid onset	Phase 2	Data in the second half of 2016
CERC-501	Substance use disorders Mood and anxiety disorders	Phase 2	Data in the second half of 2016
CERC-406	Residual cognitive impairment symptoms in MDD	Preclinical	IND submission (timing dependent on additional funding)

CERC-301

Adjunctive Treatment of Major Depressive Disorder

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 preclinical 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, which was funded by the NIMH, 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 or a conclusion can be made that the drug is not working for the patient. 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 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 Bernadeta Szewczyk and others. 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 an oral and specific NR2B antagonist that we are currently developing as a novel oral adjunctive medication for patients with severe MDD who are failing to achieve an adequate response to their current antidepressant treatment. We believe CERC-301 may have a rapid onset of effect, be well tolerated and 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 would lead to improved compliance and outcomes. We believe an antidepressant with rapid onset of effect would have the potential to provide its greatest benefit by quickly relieving suicidal ideation, a risk factor for suicide. Studies have shown that approximately 50% to 70% of severely depressed patients have experienced suicidal ideation.

We acquired MK-0657, which is now known as CERC-301, from Merck in 2013 through an exclusive worldwide license. We believe that its specific 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 and mental status changes. Preliminary trials of CERC-301 by Merck in healthy subjects failed to demonstrate clinically significant changes in mental status, although 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 some of the following advantages over ketamine and other non-selective NMDA antagonists:

- minimal, if any, psychotomimetic effects, such as 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

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 an ongoing Phase 2 randomized, double blinded placebo-controlled trial. We will evaluate the antidepressant effect of 12 mg and 20 mg doses of CERC-301 and ultimately 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. Enrollment of this trial commenced in August 2015 and we expect to release top-line data in the second half of 2016.

Study Design: Clin301-203 includes two dose administrations seven days apart, followed by 14 days of observation, for a total study duration of 21 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, known as the Bech-6, of the HAMD-17, a widely used 17-item depression rating scale. This approach is designed to 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 a 7-item unidimensional subset of the HAMD-17 known as 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 is being performed in subjects with MDD currently experiencing a severe depressive episode despite current stable treatment with either a SSRI or SNRI. Subjects are being screened directly from psychiatric clinic referrals, from depression clinical study databases, and from advertising. Potential subjects are being screened by the study sites for all inclusion, exclusion and diagnostic criteria in order to determine eligibility for the study. Subjects are also being screened via an independent third party to determine eligibility.

Adjunctive Therapy: CERC-301 is being 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.

Future Clinical Development

Upon completion of Clin301-203 we plan to engage the FDA in an end-of-phase 2 meeting with the FDA to align plans and activities for potential regulatory approval, which would include Phase 3 clinical trials, non-clinical NDA enabling studies and manufacturing activities.

CERC-501

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%) 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% 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% 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 a major public health problem.

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.

Co-Occurring Disorders

Without considering nicotine dependence, there are an estimated five 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 non-selective opioid antagonist naltrexone, an FDA-approved medication for alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to treatment initiation, is not FDA approved as an antidepressant or an antianxiety 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 significant unmet 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 attenuated symptoms associated with withdrawal, such as anxiety behaviors. The therapeutic potential of KOR antagonism has been suggested in animal models of anhedonia, depression, and anxiety, and KOR antagonists reduced the signs of nicotine, heroin and alcohol withdrawal in rodent models of dependence. In these studies, stress-induced reinstatement to drug seeking was blunted in mice who had their KOR system genetically deleted, and was also blocked in wild-type mice by treatment with nor-BNI and rats treated with JDTic. In the studies summarized by Lalanne et al., KOR antagonists reduced 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 may have antidepressant- and antianxiety- like effects, reduce addictive substance consumption, and reduce behaviors and signs of drug withdrawal. These studies provide the basis for further evaluation of the use of KOR antagonists, like CERC-501, in mood and substance use disorders, including co-occurring disorders.

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 selective, potentially well tolerated and oral

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.

Our Program

Current Development Status

In the long term, we intend to target our development efforts at the treatment of co-occurring disorders, an under-served segment of patients. We believe CERC-501 has potential as a treatment for substance use disorders, as a once-a-day, oral adjunctive treatment of MDD, and as a treatment for co-occurring disorders. We further believe that CERC-501 may have the ability to provide rapid onset of antidepressant effect. As discussed below, we plan to leverage the external studies funded and conducted by third parties with our own internally funded clinical trials to evaluate the potential human utility of CERC-501 in smoking dependence, depression, cocaine dependence, and anhedonia and mood disorders.

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 15 mg of CERC-501 on tobacco withdrawal and reinstatement and assess craving, mood and anxiety during 18 hours of abstinence in 66 heavy cigarette smokers. 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 a regimen of 15 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.

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 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 latency (the number of minutes and seconds) to the 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 to ten day washout period. Subjects will then return to the clinic to begin the second period of the cross-over design to receive placebo or 15 mg CERC-501, 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 heavy cigarette smokers currently not seeking treatment. Recruitment is ongoing and subjects will be compensated for their participation in the study.

Overview of Externally Funded and Conducted Studies

In connection with our in-license of CERC-501 from Lilly, we expect to receive the results of two external clinical trials that are currently enrolling subjects. One of these studies is funded by a grant from the NIMH and the other is privately-funded without any cost to us. The following is a summary of these two clinical trials:

- *Impact of the KOPr Antagonist OpRA Kappa in Persons at Specific Stages of Cocaine Addiction Trajectory, Versus Normal Volunteers*. This single site trial, 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.

- *A Phase 2 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 principal investigator of this 6 site clinical study, which began in 2015.

Depending on the results of Phase 2 studies for CERC-501, we may consider conducting or sponsoring one or both of these trials. In January 2016, the National Institutes of Health discontinued an ongoing Phase 2 trial for CERC-501 for treatment-resistant depression, *Double-Blind, Placebo Controlled, Proof-of-Concept (POC) Trial of LY246302, a Kappa Selective Opioid Receptor Antagonist, and Augmentation of Antidepressant Therapy in Treatment-Resistant Depression,* which was being funded by the NIMH, due to slow study progression.

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 2 study in nicotine dependent smokers. In addition, funding permitting 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 externally funded CERC-501 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 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

potential applicability in treating subjects with neuropsychiatric conditions, including MDD, schizophrenia, Parkinson's disease and pathological gambling. We believe compounds from this platform 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. We have selected CERC-406 as our first preclinical candidate from the COMTi platform. We anticipate establishing the data set necessary to select additional preclinical lead candidates 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

The neurotransmitter systems that are involved in executive function include acetylcholine, serotonin, dopamine, glutamate and histamine. Most of these targets have a wide ranging impact on different brain functions or areas, and accordingly, most drug development efforts targeting these systems 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 potential 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 facilitate 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 observed to be linked to reduced aspects of executive function in healthy volunteers and in disorders associated with cognitive impairment. We believe that targeting this genotype might produce a significant improvement in magnitude and reliability of drug response when used as an adjunctive to other treatments.

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 may be easily obtained in clinical studies via a spinal tap, or lumbar puncture, to measure concentrations of HVA and DOPAC. This facilitates immediate measures of central dopamine breakdown.

Our COMTi platform comprises COMT inhibitors with selectivity for membrane bound COMT, the dominant form of COMT found within the central nervous system. We believe these potent COMT inhibitors may selectively increase dopamine levels in the PFC, thereby improving executive function. We believe our selective COMT inhibitors may avoid off-target toxicity and side effects seen with the previous generation of COMT inhibitors, such as liver toxicity observed in tolcapone and diarrhea observed with entacapone and tolcapone. Our novel COMT inhibitors 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 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 Impairment Symptoms in Major Depressive Disorder

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. We believe there is a subgroup of patients 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.

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.

Our Solution

CERC-406 is a small, orally active molecule and is a selective COMT inhibitor with low inhibitory activity on peripheral COMT. We are anticipating to develop CERC-406 as an oral adjunctive medication for patients with residual cognitive impairment symptoms suffering from MDD. We selected CERC-406 as our lead preclinical candidate from our COMTi platform because in preclinical testing we observed that it had lower potential of peripheral, off target side effects, rapid absorption and bioavailability, good brain penetration and a favorable dose-dependent biomarker profile in rats. We have also observed that CERC-406 has an off-rate on brain COMT that is slower than tolcapone, potentially implying a good duration of effect. In preclinical 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 may:

- 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 anticipating 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 may be associated with improved functional outcomes.

Current Development Status

We anticipate to advance the characterization of the safety and efficacy of CERC-406 in preclinical animal studies, to advance manufacturing of product for potential clinical trials, and to file an IND for CERC-406.

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 evaluate 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 were filed in December 2015. Any patent issuing from the U.S. nonprovisional applications would 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 effective June 15, 2015. We 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. We have entered 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, 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, BioConvergence LLC, or BioConvergence. BioConvergence is a provider of a comprehensive range of services extending from pharmaceutical and clinical development through production and testing 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.

All of our drug candidates are small molecule compounds and are manufactured in 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.

License Agreements

Merck CERC-301 License

In 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 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 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 2013, we entered into an exclusive license agreement with 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.

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 has completed Phase 1 development by AstraZeneca Pharmaceuticals LP, for oral administration;

- Rapastinel is approaching Phase 3 development by Allergan plc, or Allergan, for intravenous administration;
- NRX 1074 is approaching Phase 2 development by Allergan for oral administration; and
- AV-101, an oral prodrug of 7-chlorokynurenic acid, is in Phase 2 development by VistaGen Therapeutics

CERC-501

There are no approved pharmacologic treatments for co-occurring disorders even though there are around five 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 (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 Pharmaceuticals 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.

Overall Competitive Climate and Risks

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.

For additional information on risks regarding our competition, refer to the section entitled “Risk Factors” in Item 1A of this Annual Report on Form 10-K.

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;
- 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 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 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, manufactures 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 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 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.

Employees

As of December 31, 2015, we had 13 full-time employees, seven 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.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our warrants and common stock would likely decline.

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, as well as our initial public offering in October 2015. 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. We incurred net losses of $10.5 million, $16.1 million and $13.0 million for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, we had an accumulated deficit of $53.6 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 our initial public offering in October 2015, 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. 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.

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.

We will require additional capital to finance our operations and pursue further development of our product candidates. 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. 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.

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 do not raise additional capital in sufficient amounts or on terms acceptable to us, we would be prevented from pursuing development and commercialization efforts, which would 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.

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 the offered securities 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 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. We have not analyzed the historical or potential impact of our equity financings on beneficial ownership and therefore no determination has been made on whether our NOL carryforwards are subject to the limitations described above.

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 2011. To date our operations have consisted of 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. 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.

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. 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 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 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;

- 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. For example, the National Institutes of Health discontinued a Phase 2 trial for CERC-501 for treatment-resistant depression, which was funded by the National Institute of Mental Health, due to slow study progression.

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. For example, we believe the decision by the National Institutes of Health to discontinue a Phase 2 trial for CERC-501was due in part to difficulties experienced in enrolling patients into the trial.

Difficulty or delays in patient recruitment into our trials 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;

- 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.

An 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 lead preclinical 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. We will require additional capital to finance any further development of our COMTi product candidates, such as CERC-406, and such capital may not be available on attractive terms or at all. 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 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 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;
- 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;
- 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 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 distributers, 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;
- 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 has completed Phase 2 development by Allergan Plc., or Allergan, which is being developed to be administered intravenously; NRX 1074 by Allergan 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 dose for a repeat-dose Phase 2 study; AV-101, an oral prodrug of 7-chlorokynurenic acid, is in Phase 2 development by VistaGen Therapeutics; 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 has completed two Phase 2 studies 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.

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 cause 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;

- 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.

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, 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 2 study, conducted by the same third party, would provide. Similarly, in January 2016 NIMH decided to discontinue the funding of a Phase 2 study of CERC-50` for treatment-resistant depression that was to be conducted by the National Institutes of Health and sponsored by Massachusetts General Hospital because of slow study progression.

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 Uli Hacksell, Ph.D., our Chief Executive Officer and President and Chairman of our board of directors. The loss of the services of Dr. Hacksell 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. Hacksell, 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. Hacksell’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.

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. We have adopted 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. We have adopted 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 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;
- 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 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.

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 our warrants or 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 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 our Stock

An active trading market for our common stock and warrants may not continue to develop or be sustained.

Prior to our initial public offering, there was no public market for our common stock and our warrants. Although our common stock and warrants are listed on the NASDAQ Capital Market, we cannot assure you that an active trading market for our shares or warrants will continue to develop or be sustained. As a result of this and other factors, you may be unable to resell your warrants or shares of our common stock. The lack of an active market may impair your ability to sell your warrants or shares of our common stock 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 warrants or shares of our common stock. Furthermore, an inactive market may also impair our ability to raise capital by selling the warrants or shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our warrants or shares of common stock as consideration.

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

Since our initial public offering, the market price of our warrants and shares of our common stock has been 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 warrants or shares of our common stock. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors that could negatively affect or result in fluctuations in the market price of our warrants and shares of our common stock 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;
- 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;
- warrant or share price and volume fluctuations attributable to inconsistent trading volume levels of our warrants or shares;
- announcement or expectation of additional financing efforts;
- sales of our warrants or shares of our common stock by us, our insiders or our other security holders;
- 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 warrants or shares of common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our warrants or shares of common stock;
- ratings downgrades by any securities analysts who follow our warrants or shares of common stock;
- the development and sustainability of an active trading market for our warrants or shares of common stock;
- future sales of our warrants or shares of 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;
- 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 warrants or shares of 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 warrants or shares of 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 warrants or shares of common stock less attractive to investors and adversely affect the market price of our warrants or shares of 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 our initial public 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.

We have determined 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 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 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 warrants or shares of common stock less attractive as a result, there may be a less active trading market for our warrants or shares of common stock, and the securities prices 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.

Our executive officers, directors and 5% stockholders and their affiliates beneficially own approximately 20.4% of our outstanding voting stock. As a result, these stockholders 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 may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our warrants and shares of common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their securities 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 securities prices and trading volume could decline.

The trading market for our warrants and shares of common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited, and may not sustain, research coverage by securities and industry analysts. If we do not sustain coverage of our company, the trading price for

our warrants and shares of common 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 warrants and shares of common stock or publishes inaccurate or unfavorable research about our business, our securities prices 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 warrants and shares of common stock could decrease, which could cause our securities prices and trading volume to decline.

Future sales of our warrants and shares of our common stock may depress their market price.

Sales of a substantial number of our warrants and shares of our common stock in the public market could occur at any time. If stockholders sell, or if the market perceives that our stockholders intend to sell, substantial amounts of our warrants or shares of our common stock in the public market, the market price of our warrants and our common stock could decline significantly.

Upon the completion of our initial public offering, the 4,000,000 shares of our common stock sold in the offering became freely tradable, and additional outstanding shares of our common stock will be available for sale in the public market in April 2016 following the expiration of lock-up agreements between some of our stockholders and the underwriters of our initial public offering. The representatives of the underwriters may release these stockholders from their lock-up agreements with the underwriters at any time, which would allow for earlier sales of shares in the public market.

In addition, we have filed a registration statement on Form S-8 registering the issuance of approximately 1.7 million shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 under the Securities Act in the case of our affiliates.

Additionally, the holders of an aggregate of 5,143,229 shares of our common stock have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

In connection with our initial public offering, we also sold two classes of warrants: Class A warrants representing the right to purchase one share of our common stock, which are exercisable on or before October 20, 2018, and Class B warrants representing the right to purchase one-half share of our common stock, which are exercisable on or before April 20, 2017.

The requirements of being a public company may strain our resources and divert management's attention, and our minimal public company operating experience may impact our business and stock price.

As a public company, we 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 are 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.

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.

Future sales and issuances of our warrants or shares of 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 will 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 warrants or shares of common stock.

We expect to offer stock options, restricted stock and other forms of stock-based compensation to our directors, officers and employees in the future. If any options that we issue are exercised, or any restricted stock that we may issue vests, and those shares are sold into the public market, the market price of our common stock may decline. In addition, the availability of shares of common stock for award under our equity incentive plan, or the grant of stock options, restricted stock or other forms of stock-based compensation, may adversely affect the market price of our common stock.

Holders of our warrants will have no rights as common stockholders until they acquire our common stock.

Until holders of our warrants acquire shares of our common stock upon exercise of the warrants, they will have no rights with respect to our common stock issuable upon exercise of the warrants, including the right to receive dividend payments, vote or respond to tender offers. Upon exercise of the warrants, holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Although we are required to use our best efforts to have an effective registration statement covering the issuance of the shares of common stock underlying the warrants at the time that holders of our warrants exercise their warrants, we cannot guarantee that a registration statement will be effective, in which case holders of our warrants may not be able to receive freely tradable shares of our common stock upon exercise of the warrants.

Holders of our warrants will be able to exercise the warrants and receive freely tradable shares only if (i) a current registration statement under the Securities Act relating to the shares of our common stock underlying the Warrants is then effective, or an exemption from such registration is available, and (ii) such shares of our common stock are qualified for sale or exempt from qualification under the applicable securities laws of the states in which the various holders of warrants reside. Although we have undertaken in the warrants, and therefore have a contractual obligation, to use our best efforts to maintain a current registration statement covering the shares of common stock underlying the warrants following completion of this offering to the extent required by federal securities laws, and we intend to comply with our undertaking, we may not be able to do so. If we are not able to do so, holders may not be able to exercise their warrants and receive freely tradable shares of our common stock but rather may only be able to receive restricted shares upon exercise. In addition, we have agreed to use our best efforts to register the shares of our common stock underlying the Warrants under the blue sky laws of the states of residence of the existing holders of the warrants, to the extent an exemption is not available. The value of the warrants may be greatly reduced if a registration statement covering the shares of our common stock issuable upon exercise of the warrants is not kept current or if the securities are not qualified, or exempt from qualification, in the states in which the holders of warrants reside.

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple 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 provides 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 provides 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; 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, 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

- 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 securities.

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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 to expand this office space based on our growth and employee head-count.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is listed and publicly traded on the NASDAQ Capital Market under the symbol "CERC." Our Class A warrants and Class B warrants are also listed and publicly traded on the NASDAQ Capital Market under the symbols "CERCW" and "CERCZ," respectively. Trading of our common stock and warrants commenced on November 13, 2015, the first date that shares of our common stock and warrants were publicly traded. Prior to that time, there was no public market for our common stock and warrants. The following table sets forth the high and low closing trading prices of our common stock and warrants as reported on the NASDAQ Capital Market for each quarter our common stock and warrants were traded in the year ended December 31, 2015.

Year Ended December 31, 2015

Fourth Quarter (Beginning November 13, 2015):	High	Low
Common stock	$4.50	$3.10
Class A warrants	$1.50	$0.51
Class B warrants	$0.79	$0.27

Holders

As of March 16, 2016, there were approximately 243 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

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.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Initial Public Offering of Units

Pursuant to the Registration Statement on Form S-1 (File No. 333-204905), as amended, that was declared effective by the SEC on October 14, 2015, we registered the units to be sold in our initial public offering (including 600,000 units with respect to an over-allotment option granted by us to the underwriters in the offering). Each unit consisted of one share of common stock, one Class A warrant to purchase one share of common stock at an exercise price of $4.55 per share and one Class B warrant to purchase one-half share of common stock at an exercise price of $3.90 per full share (the "units"). Maxim Group LLC acted as the sole book-running manager, and Laidlaw & Company (UK) acted as the lead manager.

On October 20, 2015, we sold a total of 4,000,000 units in the initial public offering at an initial public offering price of $6.50 per unit for gross proceeds of $26.0 million. The net proceeds of the initial public offering, after underwriting discounts, commissions and expenses, and before offering expenses, were approximately $23.6 million.

On November 23, 2015, the underwriter of the initial public offering exercised its over-allotment option for 20,000 shares of common stock, 551,900 Class A warrants to purchase one share of common stock and 551,900 Class B warrants to purchase one-half share of common stock for additional gross proceeds of $135,319.

There have been no material changes in the planned use of proceeds from our initial public offering, as described in our final prospectus filed with the SEC on October 15, 2015 pursuant to Rule 424(b)(4) under the Securities Act related to the initial public offering.

Item 6. Selected Financial Data

The following data has been derived from our audited financial statements, including the balance sheets at December 31, 2015, 2014 and 2013 and the related statements of operations for each of the three years ended December 31, 2015 and related notes appearing elsewhere in this Annual Report on Form 10-K or as previously filed with the Securities and Exchange Commission. You should be read the selected financial data set forth below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,		
Statement of Operations Data:	**2015**	**2014**	**2013**
Operating expenses:			
Research and development	$ 6,587,183	$ 12,240,535	$ 8,914,084
General and administrative	4,422,764	4,875,030	4,020,364
Loss from operations	(11,009,947)	(17,115,565)	(12,934,448)
Other income (expense):			
Change in fair value of warrant liabilities and embedded derivative liabilities	1,313,049	2,266,161	(121,115)
Interest income (expense), net	(793,205)	(1,206,187)	10,555
Total other income (expense):	519,844	1,059,974	(110,560)
Net loss	$(10,490,103)	$(16,055,591)	$(13,045,008)
Net loss attributable to common stockholders	$(10,490,103)	$ (3,521,153)	$(13,126,972)
Net loss per share of common stock, basic and diluted	$ (4.71)	$ (5.48)	$ (20.72)
Weighted-average shares of common stock outstanding, basic and diluted	2,226,023	642,052	633,669

	As of December 31,		
	2015	**2014**	**2013**
Balance Sheet Data:			
Cash and cash equivalents	$21,161,967	$ 11,742,349	$ 3,421,480
Total assets	21,657,565	12,316,894	5,075,600
Long term debt, net of current portion and discount	2,353,482	5,308,211	—
Total liabilities	8,573,838	10,302,027	3,065,642
Convertible preferred stock	—	28,345,531	19,856,633
Common stock	8,650	650	643
Additional paid-in capital	66,638,557	16,742,063	9,170,468
Total stockholders' equity (deficit)	13,083,727	(26,330,664)	(17,846,675)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company that is developing innovative drug candidates to 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 currently have three product candidates in development: CERC-301, CERC-501 and CERC-406.

CERC-301 is currently in Phase 2 development as an oral, adjunctive treatment of patients with severe major depressive disorder, or MDD, who are failing to achieve an adequate response to their current antidepressant treatment. 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 specifically 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 for smoking cessation. We intend to 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 considering conducting a Phase 2 clinical study in inadequately treated subjects with MDD currently on antidepressants. 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 lead preclinical 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 are anticipating to develop CERC-406 for the treatment of residual cognitive impairment symptoms in patients with MDD.

In addition, development of CERC-301 and CERC-501 beyond the currently ongoing Phase 2 clinical trials, will not be possible unless we secure additional funding. If we are unable to raise capital when needed or on attractive terms, we will 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 and federal grants. 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.

We were incorporated in Delaware in 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. 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. As of December 31, 2015, we had an accumulated deficit of $53.6 million. 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 have financed our operations primarily through private placements of our common and convertible preferred stock and convertible debt and our initial public offering, which closed in October 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. There can be no assurance as to whether or when we will achieve profitability.

Recent Developments

Initial Public Offering

On October 20, 2015, we closed an initial public offering of our units, or the IPO. Each unit consisted of one share of our common stock, one Class A warrant to purchase one share of our common stock at an exercise price of $4.55 per share and one Class B warrant to purchase one-half share of our common stock at an exercise price of $3.90 per full share. The Class A warrants expire on October 20, 2018 and the Class B warrants expire on April 20, 2017. The closing of the IPO resulted in the sale of 4,000,000 units at an initial public offering price of $6.50 per unit for gross proceeds of $26.0 million. The net proceeds of the IPO, after underwriting discounts, commissions and expenses, and before offering expenses, were approximately $23.6 million. On November 13, 2015, the units separated into shares of our common stock, Class A warrants and Class B warrants and began trading separately on the NASDAQ Capital Market.

On November 23, 2015, the underwriter of the IPO exercised its over-allotment option for 20,000 shares of our common stock, 551,900 Class A warrants to purchase one share of our common stock and 551,900 Class B warrants to purchase one-half share of our common stock for additional gross proceeds of $135,319.

The common stock and accompanying Class A warrants and Class B warrants have been classified within stockholders' equity (deficit) in the accompanying balance sheet.

Underwriter's Unit Purchase Option

The underwriter of the IPO received, for $100 in the aggregate, a unit purchase option, or the UPO, to purchase up to a total of 40,000 units (or 1% of the units sold in the IPO) exercisable at $7.48 per unit (or 115% of the public offering price per unit in the IPO). The units underlying the UPO will be, immediately upon exercise, separated into shares of our common stock, underwriters' Class A warrants and underwriters' Class B warrants (such warrants together referred to as the Underwriters' Warrants) such that, upon exercise, the holder of a UPO will not receive actual units but will instead receive the shares of our common stock and Underwriters' Warrants, to the extent that any portion of the Underwriters' Warrants underlying such units have not otherwise expired. The exercise prices of the underwriters' Class A warrants and underwriters' Class B warrants underlying the UPO are $5.23 and $4.49, respectively. The UPO may be exercised for cash or on a cashless basis, at the holder's option, and expires on October 14, 2020; provided, that, following the expiration of underwriters' Class B warrants on April 20, 2017, the UPO will be exercisable only for shares of common stock and underwriters' Class A warrants at an exercise price of $7.475 per unit; provided further, that, following the expiration of underwriters' Class A warrants on October 20, 2018, the UPO will be exercisable only for shares of common stock at an exercise price of $7.47. We have classified the UPO as a liability as it is a freestanding marked-to-market derivative instrument precluded from being classified in stockholders' equity. The fair value of the UPO is re-measured each reporting period and the change in fair value is recognized in the statement of operations.

Resignation of Former Chief Executive Officer

On December 17, 2015, Dr. Blake Paterson resigned as our President and Chief Executive Officer and as a member of our board of directors, in each case effective December 31, 2015. We entered into a separation agreement with Dr. Paterson pursuant to which we agreed to pay Dr. Paterson severance payments in accordance with his existing employment agreement, including severance payments equal to his last base salary of $415,000 for a period of twelve months, as well as an annual bonus for the year ended December 31, 2015 in the amount of $207,500 and an additional payment in the amount of $112,500. The severance payments were included as part of general and administrative expenses for the year ended December 31, 2015 in the accompanying statement of operations.

On December 20, 2015, Dr. Uli Hacksell, Chairman of Cerecor, was appointed Chief Executive Officer and President, effective January 1, 2016.

Components of Operating Results

Revenue

We have not generated any revenue from commercial product sales to date. 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. 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 hired and used consultants as needed to assist with our ongoing clinical trials of CERC-301 and CERC-501. As of December 31, 2015, we had seven full-time employees whom were primarily engaged in research and development.

We anticipate that our research and development costs, including the need to hire additional research and development employees, will increase in 2016 and beyond.

General and Administrative Expenses

General and administrative expenses consist primarily 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 Liability, Unit Purchase Option Liability and Investor Rights Obligation

In connection with the issuance of our term debt facility in August 2014, we issued warrants to purchase 625,208 shares of Series B convertible preferred stock. Upon the closing of our IPO, these warrants became warrants to purchase 22,328 shares of common stock, in accordance with its terms. These warrants represent a freestanding financial instrument that is indexed to an obligation, which we refer to as the Warrant Liability. These warrants are classified as a liability at fair value. This liability is remeasured at each balance sheet date and the change in fair value is recorded within our statement of operations.

Our obligation to issue additional shares of our Series B preferred stock as part of the Series B preferred stock offering was accounted for as a freestanding financial instrument, which we referred to as the Investor Rights Obligation. The Investor Rights Obligation expired upon the closing of our initial public offering in accordance with its terms, and the related liability was reduced to zero at that time. The gain on the change in fair value was recorded within our statement of operations for the year ended December 31, 2015.

As part of our initial public offering, the underwriter of our initial public offering received a unit purchase option, or UPO, to purchase up to 40,000 units, whereby a unit is comprised of one share of our common stock, one Class A warrant to purchase one share of our common stock and one Class B warrant to purchase one-half share of our common stock. The UPO is classified as a liability at its respective fair value. This liability is remeasured at each balance sheet date and the change in fair value is recorded within our statement of operations.

Interest Income (Expense), net

Interest expense is primarily related to interest payments pursuant to the terms of our term debt facility entered into in August 2014, as well as the amortization of the debt discounts and premiums and deferred financing fees in connection with 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 the audited financial statements appearing at the end of this Annual Report on Form 10-K, 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, 2015, we had $51.6 million of Federal and Maryland net operating loss, or NOL, carryforwards that will begin to expire in 2031. As of December 31, 2015, we had $1.4 million and $0.4 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. We have not analyzed the historical or potential impact of our equity financings on beneficial ownership and therefore no determination has been made whether the NOL carryforwards are subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance. 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.

Estimated Fair Value of Warrants, Unit Purchase Option and Investor Rights Obligation

Warrants for shares that are contingently redeemable are accounted for as freestanding financial instruments. These warrants are classified as liabilities on our balance sheet 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. We estimate the fair value of these warrants using a Black-Scholes option-pricing model. The significant assumptions used in preparing the option-pricing model for valuing the warrants as of December 31, 2015, included (i) volatility of 70%, (ii) risk free interest rate of 1.72%, (iii) strike price ($8.40), (iv) fair value of common stock ($3.35), and (v) expected life of 4.8 years. Significant decreases in our stock price volatility will significantly decrease the overall valuation of the warrants, while significant increases in our stock price volatility will significantly increase the overall valuation.

Our obligation to issue additional shares of our common stock arising from the 2014 Series B preferred stock offering, or the Investor Rights Obligation, is accounted for as a freestanding financial instrument. This obligation was classified as a liability on our balance sheet and was recorded at its estimated fair value. At the end of each reporting period, the change in the estimated fair value during the period was recorded as a component of other income (expense), net. The Investor Rights Obligation expired upon the closing of our initial public offering in accordance with its terms, and the related liability was reduced to zero at that time. The gain on the change in fair value was recorded within our statement of operations for the year ended December 31, 2015.

As part of our initial public offering we offered our underwriters the UPO to purchase up to an additional 40,000 units. The UPO is accounted for as a freestanding financial instrument and is recorded a liability on our balance sheet at its estimated fair value. At the end of each reporting period, the change in the estimated fair value during the period is recorded as component of other income (expense), net. We will continue to adjust this liability for changes in fair value until the earlier of expiration or the exercise of the UPO. We estimate the fair value of the UPO using a Black-Scholes option-pricing model within a Monte Carlo simulation model framework. The significant assumptions used in preparing the simulation model for the initial valuation of the UPO upon the close of our initial public offering, included (i) volatility range of 65% to 90%, (ii) risk free interest rate range of 0.03% to 1.29%, (iii) unit strike price ($7.48), (iv) underwriters' Class A warrant strike price ($5.23), (v) underwriters' Class B warrant strike price ($4.49), (vi) fair value of underlying equity ($4.98), and (vii) optimal exercise point of immediately prior to the expiration of the underwriters' Class B warrants, which occurs on April 20, 2017. The significant assumptions used in preparing the simulation model for valuing the UPO as of December 31, 2015, include (i) volatility range of 55% to 85%, (ii) risk free interest rate range of 0.14% to 1.16%, (iii) unit strike price ($7.48), (iv) underwriters' Class A warrant strike price ($5.23), (v) underwriters' Class B warrant strike price ($4.49), (vi) fair value of underlying equity ($3.35), and (vii) optimal exercise point of immediately prior to the expiration of the underwriters' Class B warrants, which occurs on April 20, 2017. Significant decreases in our stock price volatility will significantly decrease the overall valuation of the UPO, while significant increases in our stock price volatility will significantly increase the overall valuation.

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 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. 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 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. Due to the lack of sufficient historical data for the term of our options, the expected term of our options granted to employees and members of our board of directors has been estimated as the arithmetic average of the vesting term and the original contractual term of the option, 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,		
	2015	2014	2013
Risk-free interest rate	1.64 - 1.97 %	0.85 - 1.97 %	0.85 - 1.90 %
Expected term of options (in years)	5.0 - 6.25	5.0 - 6.25	6.0
Expected stock price volatility	70.0 %	70.0 %	70.0 %
Expected annual dividend yield	0.00 %	0.00 %	0.00 %

The estimates involved in the valuations include 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 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.

Determination of the Fair Market Value of Common Stock

We considered numerous objective and subjective factors in the assessment of fair value of its common stock for grants made prior to the date our common stock began trading separately on the NASDAQ Capital Market, which was November 13, 2015 and includes all grants made to date. The factors considered included the price for our convertible preferred stock that was sold to investors and the rights, preferences and privileges of our convertible preferred stock and common stock, the trading price of our units between the IPO date and November 13, 2015, our financial condition and results of operations during the relevant periods, including the status of the development of our product candidates, and the status of strategic initiatives. These estimates involve a significant level of judgment.

In the absence of a public trading market for our common stock prior to our initial public offering, our board of directors 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.

In valuing our common stock prior to our initial public offering, 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, which was prior to our initial public offering, 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 considered 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 would either be executed or abandoned. Under the PWERM, the value of each class of our stock was estimated using a probability-weighted analysis of the present value of the returns afforded to our stockholders under each of the 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 was allocated to the preferred stock to incorporate higher aggregate liquidation preferences. In the IPO scenarios, the equity value was allocated pro rata among the shares of common stock and each series of preferred stock, which caused 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 was weighted according to the board of directors' estimate of the probability of each scenario at the time the valuation was completed.

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, December 31, 2014, March 31, 2015, June 30, 2015 and September 30, 2015. In addition, our board of directors considered various 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.

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:

Date of Issuance	Number of Shares Underlying Options Granted	Exercise Price per Share	Fair Market Value per Common Share	Fair Value of Options per Share
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
10/20/2015	350,250	$ 6.49	$ 4.98	$ 2.93
11/9/2015	100,284	$ 5.80	$ 4.11	$ 2.32

Results of Operations

Comparison of the Years Ended December 31, 2015 and 2014

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	2014
	(in thousands)	
CERC-301	$ 3,110	$ 8,711
CERC-501	1,481	—
COMTi	260	761
FP01	—	28
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,367	2,277
Stock compensation expense	67	202
Other	302	262
	$ 6,587	$ 12,241

Research and development expenses decreased to $6.6 million in 2015 compared to $12.2 million in 2014. This $5.6 million decrease resulted from a $5.6 million decrease in external research and development costs for CERC-301. A Phase 2 clinical trial for CERC-301 was completed in 2014 and, due to the failed results in an 8 mg study for CERC-301, we initiated a second Phase 2 trial later in 2015, increasing the dosage. External research and development costs for COMTi also decreased in 2015 by $0.5 million due to a reduction in pre-clinical trial activity. There was also a decrease of $0.9 million in salaries, benefits and related costs due to a reduction in headcount. These decreases were offset by the in-licensing of CERC-501 in February 2015 for $1.1 million and an additional $0.4 million in development costs for CERC-501 thereafter.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	2014
	(in thousands)	
Salaries, benefits and related costs	$ 2,326	$ 1,619
Legal, consulting and other professional expenses	1,289	1,776
Stock compensation expense	328	885
Other	480	595
	$ 4,423	$ 4,875

General and administrative expenses decreased to $4.4 million in 2015 compared to $4.9 million in 2014. Stock compensation expense decreased by $0.6 million due to certain awards to board members and company executives made in 2014 that were fully vested at the time of the award. Legal, consulting and other professional expenses decreased by $0.5 million, driven by the write-off of deferred offering costs in 2014 of $1.1 million when we had determined that our initial public offering was no longer probable of being consummated at such time, offset by increases in board member fees, D&O insurance expense, recruiting expense, accounting and audit fees, legal fees and consulting expenses totaling $0.6 million, primarily as a result of becoming a public company in 2015. Salaries, benefits and related costs increased by $0.7 million, which was driven by $0.5 million of accrued severance expense due to the resignation of our former CEO.

Change in Fair Value of Warrant Liability, Unit Purchase Option Liability and Investor Rights Obligation

We recognized a gain on the change in fair value of our warrant liability, unit purchase option liability and investor rights obligation of $1.3 million during the year ended December 31, 2015 compared to a gain of $2.3 million during the year ended December 31, 2014. The $1.3 million gain on the change in fair value in 2015 is driven by the expiration of the investor rights obligation in October 2015 upon the closing of our initial public offering.

The $2.3 million gain on the change in fair value in 2014 was driven by the issuance of warrants for shares of Series B convertible preferred stock and the investor rights obligation and their respective changes in fair value during the year due to the gain recognized from marking the warrants for shares of Series A-1 convertible preferred stock to market.

Interest Expense, Net

Net interest expense decreased by $0.4 million for the year ended December 31, 2015 compared to the year ended December 31, 2014. The decrease is primarily due to the interest on the convertible promissory notes and demand notes we entered into in 2014. The convertible promissory notes and demand notes converted to Series B convertible preferred stock upon the completion of the Series B convertible preferred stock equity offering, and as such there is no comparable expense in 2015. This was offset by an increase in interest expense under our secured term loan facility that was entered into in August 2014.

Comparison of the Years Ended December 31, 2014 and 2013

Research and Development Expenses

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

	Year Ended December 31,	
	2014	2013
	(in thousands)	
CERC-301	$ 8,711	$ 2,717
COMTi	761	353
FP01	28	2,990
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	2,277	1,857
Stock compensation expense	202	166
Other	262	831
	$ 12,241	$ 8,914

Research and development expenses increased to $12.2 million in 2014 compared to $8.9 million in 2013, an increase of $3.3 million. 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 $0.5 million related to compensation and benefits related to personnel and related costs in 2014 as compared to 2013 driven by management's decision in 2013 to revoke its right to bonus payout for the 2012 and a portion of the 2013 bonus periods. Other research and development costs decreased by $0.6 million due primarily to costs incurred in 2013 for a research project on a compound that was discontinued.

General and Administrative Expenses

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

	Year Ended December 31,	
	2014	2013
	(in thousands)	
Salaries, benefits and related costs	$ 1,619	$ 1,329
Legal, consulting and other professional expenses	1,776	1,226
Stock compensation expense	885	583
Other	595	882
	$ 4,875	$ 4,020

General and administrative expenses increased to $4.9 million in 2014 compared to $4.0 million in 2013, an increase of $0.9 million. Salaries, benefits and related costs increased by $0.3 million due to an increase in headcount in 2014 compared to 2013, as well as management's decision in 2013 to revoke its right to bonus payout for the 2012 and a portion of the 2013 bonus periods. Legal, consulting and other professional expenses increase in 2014 as we incurred $0.6 million in additional consulting and professional fees in connection with the initial submission of our registration statement. Additionally, stock compensation expense increased by $0.3 million in 2014 primarily due to option awards that were fully vested at the time of the award. These increases were offset by a $0.3 million reduction in other general and administrative expenses due to decreased marketing and business development expenses in 2014.

Change in Fair Value of Warrant Liability and Investor Rights Obligation

We recognized a gain on the change in fair value of our warrant liability and investor rights obligation of $2.3 million in 2014 compared to a loss of $0.1 million in 2013. The $2.3 million gain on the change in fair value in 2014 was driven by the issuance of warrants for shares of Series B convertible preferred stock and the investor rights obligation and their respective changes in fair value during the year due to the gain recognized from marking the warrants for shares of Series A-1 convertible preferred stock to market.

Interest Expense, Net

Net interest expense increased by $1.2 million for the year ended December 31, 2014 compared to the year ended December 31, 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 $10.5 million, $16.1 million and $13.0 million for the years ended December 31, 2015, 2014 and 2013, respectively. At December 31, 2015, we had an accumulated deficit of $53.6 million, net working capital of $15.8 million and cash and cash equivalents of $21.2 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, as well as our initial public offering in October 2015. Based on our research and development plans we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We anticipate funding our operations over the next several years from further offerings of equity and debt securities, as well as non-dilutive financing arrangements such as federal grants or collaboration agreements.

Term Loan

In August 2014, we received a $7.5 million secured term loan from a finance company. The loan is secured by a lien on all of our assets, excluding intellectual property, which was subject to a negative pledge. The loan contains certain additional nonfinancial covenants. In connection with the loan agreement, our 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 our 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 interest rate effective from loan inception to December 16, 2015 was 7.95%. Effective December 17, 2015, the prime rate as reported by The Wall Street Journal increased 0.25% resulting in an increase to the current interest rate, which is now 8.20%. The loan was interest-only for nine months, and is repayable in equal monthly payments of principal and interest of approximately $305,000 over 27 months, which began in June 2015. The loan terminates in the third quarter of 2017 and has an outstanding balance as of December 31, 2015 of $5.7 million.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$(10,163)	$(15,518)	$(11,485)
Investing activities	(20)	(20)	(29)
Financing activities	19,603	23,859	5,416
Net increase (decrease) in cash and cash equivalents	$ 9,420	$ 8,321	$ (6,098)

Net cash used in operating activities

For the year ended December 31, 2015, our net cash used in operating activities was $10.2 million and consisted primarily of a net loss of $10.5 million, a non-cash $1.3 million gain on the change in fair value of the warrant liability, unit purchase option liability and investor rights obligation driven by the expiration of the investor rights obligation during the year of $1.1 million and a decrease in accounts payable of $0.3 million. These were offset by a $1.1 million increase in accrued expenses due to increased clinical trial activities and $0.5 million of accrued severance expense due to the resignation of our former CEO, non-cash stock compensation expense of $0.4 million and non-cash interest expense of $0.3 million.

For the year ended December 31, 2014, our net cash used in operating activities was $15.5 million and consisted primarily of a net loss of $16.1 million, a non-cash $2.3 million gain on the change in fair value of the warrant liability and investor rights obligation and a decrease in accounts payable of $0.7 million. These were offset by non-cash stock compensation expense of $1.1 million, the write off of deferred public offering costs of $1.1 million, non-cash interest expense of $1.0 million and a decrease in prepaid expenses and other current assets of $0.4 million.

For the year ended December 31, 2013, our net cash used in operating activities was $11.5 million and consisted primarily of a net loss of $13.0 million, an increase in prepaid expenses and other current assets of $0.3 million and an increase in restricted cash of $0.2 million. These were offset by non-cash stock compensation expense of $0.7 million and a $1.1 million increase in accounts payable and accrued expenses due primarily to increased clinical trial activities.

Net cash used in investing activities

Net cash used in investing activities is limited to purchases of property and equipment consisting of computers and software and furniture and equipment. Our net cash used in investing activities was $20,000, $20,000, and $29,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

Net cash provided by financing activities

For the year ended December 31, 2015, our net cash provided by financing activities was $19.6 million and consisted primarily of proceeds from our initial public offering including the over-allotment option, net of underwriting discounts, commissions and expenses of $23.7 million offset by the payment of offering costs related to the initial public offering of $2.3 million, and principal payments on our term loan of $1.8 million.

For the year ended December 31, 2014, our net cash provided by financing activities was $23.9 million and consisted primarily of proceeds from our convertible debt, demand notes, and Series B convertible preferred stock equity issuance aggregating $17.3 million as well as $7.4 million from our term loan entered into in August 2014. These proceeds were offset by the payment of $0.4 million in financing fees related to the equity and debt financing and $0.4 million for IPO-related deferred offering costs.

For the year ended December 31, 2013, our net cash provided by financing activities was $5.4 million and consisted primarily of 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.

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 the development of our programs. Following the closing of our initial public offering in October 2015, we expect to incur significant legal, accounting and other expenses that we were not previously 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 were previously 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 we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. 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, grant funding and exploring the possibility of entering into collaboration agreements.

We may need to raise substantial additional capital 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 may 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;
- 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; and
- 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

Please refer to the section entitled "Risk Factors" at Item 1A of this Annual Report on Form 10-K 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, 2015 (in thousands):

Contractual Obligation(1)	Total	Less than one year	1 - 3 years	3 - 5 years	More than 5 years
Debt obligations(2)	$5,994	$ 3,663	$ 2,331	$ —	$ —
Operating lease obligations(3)	465	151	314	—	—
Total contractual obligations	$6,459	$ 3,814	$ 2,645	$ —	$ —

(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.

We have also entered into agreements with contract research organizations, or CROs, and other external service providers for services, primarily in connection with the clinical trials and development of our product candidates. We were contractually obligated for up to approximately $3.6 million of future services under these agreements as of December 31, 2015. Our actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

Off-Balance Sheet Arrangements

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

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 but given that we do not

currently have any commercial sales or revenue from collaboration agreements, we do not expect this will have any impact on our historical 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.

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 early adopted this guidance during the year ended December 31, 2014 and have properly applied it the 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 year ended December 31, 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, 2015. 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. Management will perform an evaluation of internal control over financial reporting next year as of December 31, 2016.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We maintain a short-term investment portfolio consisting mainly of highly liquid short-term money market funds, which we consider to be cash equivalents. These investments earn interest at variable rates and, as a result, decreases in market interest rates would generally result in decreased interest income. We do not believe that a 10% increase or decrease in interest rates would have a material effect on the fair value of our investment portfolio due to the short-term nature of these instruments, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of December 31, 2015, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2016 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2016 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2016 Annual Meeting of Stockholders and is incorporated herein by reference:

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2016 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2016 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) *Documents filed as part of this report.*

1. The following financial statements of Cerecor, Inc. and Report of Ernst & Young, LLP, Independent Registered Public Accounting Firm, are included in this report:

Report of Independent Registered Public Accounting Firm	F-3
Balance Sheets as of December 31, 2015 and 2014	F-4
Statements of Operations for the years Ended December 31, 2015, 2014 and 2013	F-5
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) for the period from January 1, 2013 to December 31, 2015	F-6
Statements of Cash Flows for the years Ended December 31, 2015, 2014 and 2013	F-7
Notes to Financial Statements	F-8

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements described above.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) *Exhibits*. See the Exhibit Index and Exhibits filed as part of this report.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cerecor Inc.

/s/ Uli Hacksell
Uli Hacksell
President and Chief Executive Officer

Date: March 23, 2016

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Uli Hacksell, his true and lawful attorney-in-fact and agent with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Uli Hacksell **Uli Hacksell**	President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 23, 2016
/s/ Mariam E. Morris **Mariam E. Morris**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 23, 2016
/s/ Thomas Aasen **Thomas Aasen**	Director	March 23, 2016
/s/ Eugene A. Bauer **Eugene A. Bauer**	Director	March 23, 2016
/s/ Isaac Blech **Isaac Blech**	Director	March 23, 2016
/s/ Phil Gutry **Phil Gutry**	Director	March 23, 2016
/s/ Magnus Persson **Magnus Persson**	Director	March 23, 2016
/s/ Behshad Sheldon **Behshad Sheldon**	Director	March 23, 2016

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, 2015 and 2014, and the related statements of operations, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2015. 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, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Baltimore, Maryland

March 23, 2016

CERECOR INC.

Balance Sheets

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$ 21,161,967	$ 11,742,349
Prepaid expenses and other current assets	401,550	360,307
Restricted cash—current portion	58,832	58,333
Total current assets	21,622,349	12,160,989
Restricted cash, net of current portion	—	117,165
Property and equipment, net	35,216	38,740
Total assets	$ 21,657,565	$ 12,316,894
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Current portion of long term debt, net of discount	$ 3,208,074	$ 1,905,879
Accounts payable	678,109	931,139
Accrued expenses and other current liabilities	1,885,458	975,114
Warrant liability	27,606	69,684
Unit purchase option liability	50,571	—
Investor rights obligation	—	1,112,000
Total current liabilities	5,849,818	4,993,816
Long term debt, net of current portion and discount	2,353,482	5,308,211
Other long term liabilities	370,538	—
Total liabilities	8,573,838	10,302,027
Convertible preferred stock:		
Series A—$0.001 par value; zero and 31,116,391 shares authorized at December 31, 2015 and 2014, respectively; zero and 31,116,391 shares issued and outstanding at December 31, 2015 and 2014, respectively	—	10,462,885
Series A-1—$0.001 par value; zero and 9,074,511 shares authorized at December 31, 2015 and 2014, respectively; zero and 9,074,511 shares issued and outstanding at December 31, 2015 and 2014, respectively	—	3,389,331
Series B—$0.001 par value; zero and 115,000,000 shares authorized at December 31, 2015 and 2014, respectively; zero and 58,948,735 shares issued and outstanding at December 31, 2015 and 2014, respectively	—	14,493,315
Total convertible preferred stock	—	28,345,531
Stockholders' equity (deficit):		
Preferred stock—$0.001 par value; 5,000,000 and zero shares authorized at December 31, 2015 and 2014, respectively; zero shares issued and outstanding at December 31, 2015 and 2014	—	—
Common stock—$0.001 par value; 200,000,000 and 230,000,000 shares authorized at December 31, 2015 and 2014, respectively; 8,650,143 and 649,721 shares issued and outstanding at December 31, 2015 and 2014, respectively	8,650	650
Additional paid-in capital	66,638,557	16,742,063
Accumulated deficit	(53,563,480)	(43,073,377)
Total stockholders' equity (deficit)	13,083,727	(26,330,664)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 21,657,565	$ 12,316,894

See accompanying notes to financial statements.

CERECOR INC.

Statements of Operations

	Year Ended December 31,		
	2015	**2014**	**2013**
Operating expenses:			
Research and development	$ 6,587,183	$ 12,240,535	$ 8,914,084
General and administrative	4,422,764	4,875,030	4,020,364
Loss from operations	(11,009,947)	(17,115,565)	(12,934,448)
Other income (expense):			
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	1,313,049	2,266,161	(121,115)
Interest income (expense), net	(793,205)	(1,206,187)	10,555
Total other income (expense)	519,844	1,059,974	(110,560)
Net loss	$(10,490,103)	$(16,055,591)	$(13,045,008)
Net loss attributable to common stockholders	$(10,490,103)	$ (3,521,153)	$(13,126,972)
Net loss per share of common stock, basic and diluted	$ (4.71)	$ (5.48)	$ (20.72)
Weighted-average shares of common stock outstanding, basic and diluted	2,226,023	642,052	633,669

See accompanying notes to financial statements.

CERECOR INC.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

For the Period from January 1, 2013 to December 31, 2015

	Series A, A-1 and B convertible preferred stock		Stockholders' Equity (Deficit)				
			Common stock		Additional paid-in	Accumulated	Total stockholders' equity
	Shares	Amount	Shares	Amount	capital	deficit	(deficit)
Balance, January 1, 2013	31,116,391	$ 19,856,632	642,844	$ 643	$ 2,591,397	$(13,972,778)	$(11,380,738)
Issuance of Series A-1 convertible preferred stock	9,074,511	6,567,064	—	—	—	—	—
Discount for beneficial conversion feature on Series A-1 convertible preferred stock	—	(6,567,064)	—	—	6,567,064	—	6,567,064
Offering costs paid for Series A-1 convertible preferred stock issuance	—	—	—	—	(736,640)	—	(736,640)
Accretion of Series 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)
Balance, December 31, 2013	40,190,902	19,856,633	642,844	643	9,170,468	(27,017,786)	(17,846,675)
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 investor rights obligation	3,333,331	837,313	—	—	—	—	—
Issuance of Series B convertible preferred stock net of issuance costs and investor 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)
Balance, December 31, 2014	99,139,637	$ 28,345,531	649,721	$ 650	$16,742,063	$(43,073,377)	$(26,330,664)
Reverse stock split							—
Issuance of securities in initial public offering, including over-allotment and underwriters' unit purchase option, net of offering costs and underwriting discounts, commissions and expenses	—	—	4,020,000	4,020	21,161,569	—	21,165,589
Issuance of common stock for conversion of preferred stock upon closing of initial public offering	(99,139,637)	(28,345,531)	3,980,422	3,980	28,340,177	—	28,344,157
Stock-based compensation	—	—	—	—	394,748	—	394,748
Net loss	—	—	—	—	—	(10,490,103)	(10,490,103)
Balance, December 31, 2015	—	$ —	8,650,143	$ 8,650	$66,638,557	$(53,563,480)	$ 13,083,727

See accompanying notes to financial statements.

CERECOR INC.

Statements of Cash Flows

	Year Ended December 31,		
	2015	**2014**	**2013**
Operating activities			
Net loss	$(10,490,103)	$(16,055,591)	$(13,045,008)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	23,508	28,943	20,032
Loss on disposition of assets	—	17,806	—
Stock-based compensation expense	394,748	1,086,581	748,648
Write off of deferred public offering costs	—	1,064,106	—
Non-cash interest expense	293,748	989,258	—
Non-cash expense related to issuance of warrants	—	—	25,811
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	(1,313,049)	(2,266,161)	121,115
Changes in assets and liabilities:			
Prepaid expenses and other assets	(41,243)	353,973	(271,004)
Restricted cash	116,666	(498)	(175,000)
Accounts payable	(268,709)	(708,366)	818,391
Accrued expenses and other current liabilities	1,121,054	(28,400)	271,875
Net cash used in operating activities	(10,163,380)	(15,518,349)	(11,485,140)
Investing activities			
Purchase of property and equipment	(19,984)	(19,502)	(29,268)
Net cash used in investing activities	(19,984)	(19,502)	(29,268)
Financing activities			
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
Proceeds from issuance of Series B convertible preferred stock and common stock warrants, net of offering costs	—	14,584,307	—
Principal payments on term debt	(1,811,744)	—	—
Payment of fractional shares upon conversion of preferred stock to common stock	(1,373)	—	—
Proceeds from initial public offering, including over-allotment, net of underwriting discounts, commissions and expenses	23,685,270	—	—
Payment of offering costs of initial public offering	(2,269,171)	(365,253)	(698,853)
Net cash provided by financing activities	19,602,982	23,858,720	5,416,227
Increase (decrease) in cash and cash equivalents	9,419,618	8,320,869	(6,098,181)
Cash and cash equivalents at beginning of period	11,742,349	3,421,480	9,519,661
Cash and cash equivalents at end of period	$ 21,161,967	$ 11,742,349	$ 3,421,480
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 568,299	$ 173,514	$ —
Supplemental disclosures of noncash financing activities:			
Conversion of promissory and demand notes into Series B convertible preferred stock	$ —	$ 2,249,666	$ —
Reclassification of common stock warrants from liabilities to equity	$ —	$ 426,303	$ —
Allocation of debt and equity proceeds to investor rights obligation	$ —	$ 2,598,510	$ —
Extinguishment upon modification of Series A and A-1 convertible preferred stock	$ —	$ 12,534,438	$ —

See accompanying notes to financial statements.

1. Business

Description of Business and Organization

Cerecor Inc. (the "Company" or "Cerecor") was incorporated on January 31, 2011 in Delaware. 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 has incurred recurring operating losses since inception. For the year ended December 31, 2015, the Company incurred a net loss of $10.5 million and generated negative cash flows from operations of $10.2 million. As of December 31, 2015, the Company had an accumulated deficit of $53.6 million. 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. In October 2015, the Company completed its initial public offering of units ("IPO"), selling 4,000,000 units at an offering price of $6.50 per share, resulting in gross proceeds of $26.0 million and net proceeds from the offering of approximately $23.6 million, after deducting underwriting discounts, commissions and expenses (see Note 9). 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 believes that its cash and cash equivalents will be sufficient to meet its anticipated cash requirements through at least the next twelve months.

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 Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

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, warrant liability and embedded derivative liabilities. 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.

Prior to being a public company, the Company utilized estimates and assumptions in determining the fair value of its common stock as an input for determining the grant date fair value of stock option grants. Management used the assistance of a third-party valuation firm in estimating the fair value of the common stock. The board of directors 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, if any, of preferred stock, the 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 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, the investor rights obligation, warrants on preferred stock and 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, the 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 generally 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, 2015, 2014 and 2013.

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.

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.

Property and Equipment

Property and equipment consists of computers, office 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 would compare 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 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 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 11) 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, 2015, the Company does not believe any material uncertain tax positions are present.

Stock-Based Compensation

At December 31, 2015, the Company had one stock-based compensation plan (see Note 10). The Company applies the provisions of ASC 718, *Compensation—Stock Compensation* ("ASC 718"), which 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 statements 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.

For stock options issued to non-employees, the Company initially measures the options at their grant date fair values and revalues 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 10 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 by 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 years ended December 31, 2015 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, 2017, 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, although, the impact is not expected to be significant given the Company has not historically recognized significant amounts of revenue.

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). The Company early adopted this guidance during the year ended December 31, 2014 and, as a result, inception-to-date information about the statements of operations, cash flows, and stockholders' deficit is no longer presented.

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 adoption 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 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 adopted this guidance beginning with 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. 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.

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 years ended December 31, 2015, 2014 and 2013:

Net loss per share, basic and diluted calculation:	Year ended December 31, 2015	Year ended December 31, 2014	Year ended December 31, 2013
Net loss	$(10,490,103)	$(16,055,591)	$(13,045,008)
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	$(10,490,103)	$ (3,521,153)	$(13,126,972)
Weighted-average common shares outstanding	2,226,023	642,052	633,669
Net loss per share, basic and diluted	$ (4.71)	$ (5.48)	$ (20.72)

The following outstanding securities at December, 31, 2015, 2014 and 2013 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	December 31, 2015	December 31, 2014	December 31, 2013
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	959,188	552,726	381,669
Warrants on common stock	7,400,934	681,858	512,686
Warrants on preferred stock	—	625,208	—
Investor rights obligation	—	53,351,117	—
Underwriters' unit purchase option	40,000	—	—

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.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

At December 31, 2015 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 term loan warrant liability, the investor rights obligation and the underwriters' unit purchase option 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 $5.7 million as of December 31, 2015 was based on current interest rates for similar types of borrowings and is in Level 2 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, 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)
Assets			
Investments in money market funds*	$ 21,122,553	$ —	$ —
Liabilities			
Warrant liability	$ —	$ —	$ 27,606
Unit purchase option liability	—	$ —	$ 50,571

	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)
Assets			
Investments in money market funds*	$ 11,251,724	$ —	$ —
Liabilities			
Investor rights obligation	$ —	$ —	$1,112,000
Warrant liability	—	$ —	$ 69,684

* 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 common stock as part of the term loan agreement) is 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 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, 2015, include (i) volatility of 70%, (ii) risk free interest rate of 1.72%, (iii) strike price ($8.40), (iv) fair value of common stock ($3.35), and (v) expected life of 4.8 years.

The underwriters' unit purchase option (the "UPO") was issued to the underwriters of the IPO and provides the underwriters the option to purchase up to a total of 40,000 units. The units underlying the UPO will be, immediately upon exercise, separated into shares of common stock, underwriters' Class A warrants and underwriters' Class B warrants (such warrants together referred to as the Underwriters' Warrants). The Underwriters' Warrants are warrants to purchase shares of common stock (see Note 9 for additional information on the UPO). The Company classifies the UPO as a liability as it is a freestanding marked-to-market derivative instrument that is precluded from being classified in stockholders' equity. The UPO liability is 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 UPO is exercised, expire or other facts and circumstances lead the UPO to be reclassified to stockholders' equity. The fair value of the UPO liability is estimated using a Black-Scholes option-pricing model within a Monte Carlo simulation model framework. The significant assumptions used in preparing the simulation model for the initial valuation of the UPO liability upon the close of the Company's initial public offering, include (i) volatility range of 65% to 90%, (ii) risk free interest rate range of 0.03% to 1.29%, (iii) unit strike price ($7.48), (iv) underwriters' Class A warrant strike price ($5.23), (v) underwriters' Class B warrant strike price ($4.49), (vi) fair value of underlying equity ($4.98), and (vii) optimal exercise point of immediately prior to the expiration of the underwriters' Class B warrants, which occurs on April 20, 2017. The significant assumptions used in preparing the simulation model for valuing the UPO as of December 31, 2015, include (i) volatility range of 55% to 85%, (ii) risk free interest rate range of 0.14% to 1.16%, (iii) unit strike price ($7.48), (iv) underwriters' Class A warrant strike price ($5.23), (v) underwriters' Class B warrant strike price ($4.49), (vi) fair value of underlying equity ($3.35), and (vii) optimal exercise point of immediately prior to the expiration of the underwriters' Class B warrants, which occurs on April 20, 2017. The decreases in volatility and the fair value of underlying equity were the primary drivers of the decrease in fair value of the UPO liability from $209,542 as of the initial valuation upon the closing of the Company's initial public offering to $50,571 as of December 31, 2015. This $158,971 gain on the change in fair value of the UPO liability was recorded to other income in the accompanying statement of operations.

The investor rights obligation expired in October 2015 upon the closing of the Company's IPO. While outstanding, the investor rights obligation was remeasured at each reporting period and changes in fair value were recorded as a component of other income (expense) in the Company's statements 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 of 60%, (ii) risk free interest rate ranging from 0.05% to 0.63%, (iii) strike price ($8.40), (iv) fair value of preferred stock ranging from $0.00 to $5.04, and (v) expected life ranging from 0.5 to 1.75 years.

The tables presented below are a summary of changes in the fair value of the Company's Level 3 valuation for the warrant liability, unit purchase option liability and investor rights obligation for the years ended December 31, 2015 and 2014:

	Warrant liability	Unit purchase option liability	Investor rights obligation	Total
Balance at December 31, 2014	$ 69,684	$ —	$ 1,112,000	$ 1,181,684
Issuance of unit purchase option	—	209,542	—	209,542
Expiration of investor rights obligation	—	—	(1,112,000)	(1,112,000)
Change in fair value	(42,078)	(158,971)	—	(201,049)
Balance at December 31, 2015	$ 27,606	$ 50,571	$ —	$ 78,177

	Warrant liability	Unit purchase option liability	Investor rights obligation	Total
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 obligation 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	$ 69,684	$ —	$ 1,112,000	$ 1,181,684

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2015 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, 2015 and 2014.

5. Property and Equipment

Property and equipment as of December 31, 2015 and 2014 consisted of the following:

	December 31,	
	2015	2014
Furniture and equipment	$ 34,918	$ 34,918
Computers and software	61,133	41,150
Total property and equipment	96,051	76,068
Less accumulated depreciation	(60,835)	(37,328)
Property and equipment, net	$ 35,216	$ 38,740

Depreciation expense was $23,508 and $28,943 for the years ended December 31, 2015 and December 31, 2014, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2015 and 2014 consisted of the following:

	December 31,	
	2015	2014
Compensation and benefits	$1,128,073	$129,450
Research and development expenses	464,719	598,883
General and administrative	253,132	159,045
Accrued interest	39,534	87,736
Total accrued expenses and other current liabilities	$1,885,458	$975,114

7. Asset Acquisition and License Agreements

Merck CERC-301 License

In 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 $1.5 million. 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 statements 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.

Lilly CERC-501 License

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 (or "Lilly"). 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 statements of operations for the year ended December 31, 2015. Upon the Company undertaking a nine-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. 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.

For the first KOR product the Company develops, it is required to make milestone payments in an amount not to exceed, in the aggregate, $19 million 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 million. Upon commercialization of a KOR product, the Company will pay 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 the Company 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.

Merck COMTi License

In 2013, the Company entered into a separate exclusive license agreement with Merck pursuant to which Merck granted the Company certain rights in small molecule compounds which are known to inhibit the activity of COMT. In consideration of the license, the Company made a $200,000 upfront payment to Merck. For each COMT product that is developed, the Company is required to pay up to $6.2 million in milestone payments upon achievement of various development and regulatory milestones. Upon commercialization of a COMT product, the Company is required to pay Merck a royalty of a low single digit on net sales. 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 the Company under the license agreement covering the COMT product in such country, or (ii) ten years from the first commercial sale of the COMT product in such country.

8. 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 interest rate effective from loan inception to December 16, 2015 was 7.95%. Effective December 17, 2015, the prime rate as reported by The Wall Street Journal increased 0.25% resulting in an increase to the current interest rate, which is now 8.20%. The loan was interest-only for nine months, and is repayable in equal monthly payments of principal and interest of approximately $305,000 over 27 months, which began in June 2015. Debt consisted of the following as of December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014
Term loan	$ 5,688,256	$ 7,500,000
Less: debt discount	(126,700)	(285,910)
Term Loan, net of debt discount	5,561,556	7,214,090
Less: current portion, net of debt discount	(3,208,074)	(1,905,879)
Long term debt, net of current portion and debt discount	$ 2,353,482	$ 5,308,211

Interest expense, which includes amortization of a discount and the accrual of a termination fee, was approximately $800,000 and $329,000 for the years ended December 31, 2015 and 2014, respectively, in the accompanying statements of operations. Future principal payments are as follows:

Year ending December 31,	
2016	$ 3,314,225
2017	2,374,031
	$ 5,688,256

In connection with the term loan, the Company issued warrants 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 five years following the Company's IPO, which is October 2020. Upon the closing of the Company's IPO, these warrants became warrants to purchase 22,328 shares of common stock at an exercise price of $8.40 per share, in accordance with their terms. The Company's warrants 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 (see Note 4).

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. The lender fees and warrants 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 was $159,210 and $68,861 during the years ended December 31, 2015 and 2014, respectively. Accretion of the one-time fee was $84,144 and $36,394 during the years ended December 31, 2015 and 2014, respectively. The amortization of the debt discount and the accretion of the one-time fee are reflected as a components of interest expense within the Company's statements of operations.

9. Capital Structure

On October 20, 2015, the Company filed an amended and restated certificate of incorporation in connection with the closing of its initial public offering. The amended and restated certificate of incorporation authorizes the Company to issue two classes of stock, common stock and preferred stock, and eliminates all references to the previously existing series of preferred stock. At December 31, 2015, the total number of shares of capital stock the Company was authorized to issue was 205,000,000 of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of $0.001 per share. At December 31, 2015, there were 8,650,143 shares of common stock outstanding and zero shares of preferred stock outstanding.

Common Stock

Reverse Stock Split

On September 1, 2015, the Company filed an amendment to its amended and restated certificate of incorporation effecting a 1-for-28 reverse stock split of its common stock. 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' equity (deficit) reflects the reverse stock split by reclassifying from common stock to additional paid-in capital an amount equal to the par value of the decreased shares resulting from the reverse stock split.

Initial Public Offering

On October 20, 2015, the Company closed an initial public offering of its units (the "IPO"). Each unit consisted of one share of common stock, one Class A warrant to purchase one share of common stock at an exercise price of $4.55 per share and one Class B warrant to purchase one-half share of common stock at an exercise price of $3.90 per full share (the "units"). The Class A warrants expire on October 20, 2018 and the Class B warrants expire on April 20, 2017. The closing of the IPO resulted in the sale of 4,000,000 units at an initial public offering price of $6.50 per unit for gross proceeds of $26.0 million. The net proceeds of the IPO, after underwriting discounts, commissions and expenses, and before offering expenses, to the Company were approximately $23.6 million. On November 13, 2015, the units separated into common stock, Class A warrants and Class B warrants and began trading separately on the NASDAQ Capital Market.

On November 23, 2015, the underwriter of the IPO exercised its over-allotment option for 20,000 shares of common stock, 551,900 Class A warrants to purchase one share of common stock and 551,900 Class B warrants to purchase one-half share of common stock for additional gross proceeds of $135,319.

The common stock and accompanying Class A warrants and Class B warrants have been classified to stockholders' equity (deficit) in the Company's balance sheet.

Underwriter's Unit Purchase Option

The underwriter of the IPO received, for $100 in the aggregate, a unit purchase option (the "UPO") to purchase up to a total of 40,000 units (or 1% of the units sold in the IPO) exercisable at $7.48 per unit (or 115% of the public offering price per unit in the IPO). The units underlying the UPO will be, immediately upon exercise, separated into shares of common stock, underwriters' Class A warrants and underwriters' Class B warrants (such warrants together referred to as the Underwriters' Warrants) such that, upon exercise, the holder of a UPO will not receive actual units but will instead receive the shares of common stock and Underwriters' Warrants, to the extent that any portion of the Underwriters' Warrants underlying such units have not otherwise expired. The exercise prices of the underwriters' Class A warrants and underwriter's Class B warrants underlying the UPO are $5.23 and $4.49, respectively. The UPO may be exercised for cash or on a cashless basis, at the holder's option, and expires on October 14, 2020; provided, that, following the expiration of underwriters' Class B warrants on April 20, 2017, the UPO will be exercisable only for shares of common stock and underwriters' Class A warrants at an exercise price of $7.475 per unit; provided further, that, following the expiration of underwriters' Class A warrants on October 20, 2018, the UPO will be exercisable only for shares of common stock at an exercise price of $7.47. The Company classified the UPO as a liability as it is a freestanding marked-to-market derivative instrument that is precluded from being classified in stockholders' equity. The fair value of the UPO is re-measured each reporting period and the change in fair value is recognized in the statement of operations (see Note 4).

Voting

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 common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

The holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of the Company's common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all debts and other liabilities.

Rights and Preferences

Holders of the Company's common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the Company's common stock.

Convertible Preferred Stock

Preferred Stock Conversion

Upon the closing of the IPO in October 2015, each share of Series A convertible preferred stock was converted into 0.04464 shares of common stock, each share of Series A-1 convertible preferred stock was converted into 0.05357 shares of common stock and each share of Series B convertible preferred stock was converted into 0.03571 shares of common stock. As a result, the outstanding preferred stock as of the closing of the IPO converted into 3,980,422 shares of common stock.

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 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 May 18, 2012, the Company completed a direct private placement of its Series A convertible preferred stock in the amount of $1.2 million. 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. 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. The net proceeds to the Company from these Series A convertible preferred stock issuances after offering costs was approximately $17.7 million.

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, the 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 of Series A-1 convertible preferred stock. 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. The net proceeds to the Company after offering costs were approximately $6.1 million.

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.

Series B Convertible Preferred Stock Transaction

In July 2014, pursuant to the terms of the agreement, the Company completed an initial closing of an equity offering for 46,684,455 shares of its Series B convertible preferred stock at an original issuance price of $0.2999 per share for gross proceeds of $14.0 million. The Company also issued demand notes in July 2014, with an aggregate principal balance of $1.0 million, which were converted into 3,333,331 shares of Series B convertible preferred stock at an original issuance price of $0.2999 per share for additional gross proceeds of $1.0 million. 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 at a conversion price of $0.2249 per share for an aggregate amount of $1.3 million.

In August 2014, the Company completed a second closing of an equity offering for shares of its Series B convertible preferred stock with its 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 additional gross proceeds of $1.0 million.

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 statements 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 $2.6 million. The investor rights obligation expired in October 2015 upon the closing of the Company’s IPO and the Company recognized a gain on the change in fair value of $1.1 million, which was recorded as other income in the accompanying statements of operations.

Common Stock Warrants

At December 31, 2015, the following common stock warrants were outstanding:

Number of shares underlying warrants	Exercise price per share	Expiration date
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
2,275,950	$ 3.90	April 2017
20,000	$ 4.49	April 2017
14,284	$ 28.00	July 2017
80,966	$ 28.00	August 2018
4,551,900	$ 4.55	October 2018
40,000	$ 5.23	October 2018
3,571	$ 28.00	December 2018
22,328	$ 8.40	October 2020
2,380	$ 8.68	May 2022
7,400,934		

Series B Convertible Preferred Stock Warrants

In August 2014, warrants to purchase 625,208 shares of Series B convertible preferred stock, at an exercise price equal to $0.2999 per share, were issued to the term loan lender in conjunction with the loan of $7.5 million (see Note 8). Upon the closing of the Company's IPO, these warrants to purchase 625,208 shares of Series B convertible preferred stock became warrants to purchase 22,328 shares of common stock at an exercise price of $8.40 per share, in accordance with their terms. These warrants represent a freestanding financing instrument indexed to an obligation of the Company and as such is accounted for as a liability in accordance with ASC 480. The Company adjusts the carrying value of the liability, which appears as "warrant liability" on the accompanying balance sheets, to its estimated fair value at each reporting date (see Note 4).

10. 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 determined by the board of directors, upon each option grant, although certain option grants in 2015 and 2014 were fully vested on the grant date. On January 10, 2012 and May 6, 2013, the board of directors and stockholders of the Company approved amendments to the Plan authorizing increases in the number of shares reserved for issuance under the Plan of 107,143 and 418,714, respectively, resulting in an aggregate number of shares reserved for issuance under the Plan of 704,428.

2015 Omnibus Plan

On June 26, 2015, the board of directors adopted the 2015 Omnibus Plan, which was approved by the Company's stockholders on August 31, 2015, reserving and authorizing up to 890,815 new shares of common stock for issuance. The 2015 Omnibus Plan became effective upon the business day immediately preceding the date of the Company's final prospectus, which was dated October 14, 2015.

As of the date of the 2015 Omnibus Plan, the 2011 Stock Incentive Plan merged with and into the 2015 Omnibus Plan and no additional grants will be made under the 2011 Stock Incentive Plan. Outstanding grants under

the 2011 Stock Incentive Plan will continue in effect according to their terms as in effect before the 2015 Omnibus Plan merger, the shares with respect to outstanding grants under the 2011 Stock Incentive Plan will be issued or transferred under the 2015 Omnibus Plan, and the number of shares of common stock remaining available for issuance under the 2011 Stock Incentive Plan are authorized for issuance under the 2015 Omnibus Plan. As of December 31, 2015, there were 696,736 shares remaining under the Plan available for future issuance. During the term of the 2015 Omnibus Plan, the share reserve automatically increases on the first trading day in January of each calendar year, beginning in 2016, by an amount equal to 3% of the total number of outstanding shares of common stock on the last trading day in December of the prior calendar year.

The estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the employees' service periods, which is the period in which the awards vest. Stock- based compensation expense recognized for the years ending December 31, 2015 and 2014 was as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2014
Research and development	$ 67,021	$ 201,653
General and administrative	327,727	884,928
Total stock-based compensation	$394,748	$1,086,581

A summary of option activity for the years ended December 31, 2015 and 2014 is as follows:

	Options Outstanding			
	Number of shares	Weighted-average exercise price	Fair value of options granted	Weighted average remaining contractual term (in years)
Balance, January 1, 2014	381,669	$ 7.78		
Granted	177,484	$ 12.14	$ 389,538	
Forfeitures	(6,427)	$ 8.68		
Balance, December 31, 2014	552,726	$ 9.17		
Granted	523,390	$ 6.31	$1,467,886	
Forfeitures	(116,928)	$ 8.60		
Balance, December 31, 2015	959,188	$ 7.68		7.51
Vested or expected to vest at December 31, 2015	959,188	$ 7.68		7.51
Exercisable at December 31, 2015	604,167	$ 8.51		7.05

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, 2015, the aggregate intrinsic value of options outstanding, vested and expected to vest was $0. The total grant date fair value of shares which vested during the years ended December 31, 2015, 2014 and 2013 was $0.7 million, $1.3 million and $0.6 million, respectively.

The per-share weighted-average grant date fair value of the options granted during 2015, 2014 and 2013 was estimated at $2.80, $2.24 and $5.60, respectively, on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2015	2014	2013
Risk-free interest rate	1.64 - 1.97 %	0.85 - 1.97 %	0.85 - 1.90 %
Expected term of options (in years)	5.0 - 6.25	5.0 - 6.25	6.0
Expected stock price volatility	70.0 %	70.0 %	70.0 %
Expected annual dividend yield	0.00 %	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: Due to lack of sufficient historical data, the Company estimates the expected life of its stock options granted to employees and members of the board of directors as the arithmetic average of the vesting term and the original contractual term of the option. The Company estimates the expected life of its stock options granted to consultants and nonemployees to be the contractual term of the options.

- 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 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 for grants made prior to the date the Company's common stock began trading separately on the NASDAQ Capital Market, which was November 13, 2015, and includes all grants made to date. The factors considered include the price for the Company's convertible preferred stock that was sold to investors and the rights, preferences and privileges of the convertible preferred stock and common stock, the trading price of the Company's units between the IPO date and November 13, 2015, 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, 2015, there was approximately $900,890 of total unrecognized compensation expense related to unvested options granted under the Plan to be recognized as follows:

Year ending December 31,	
2016	$ 273,913
2017	262,426
2018	246,094
2019	118,457
	$ 900,890

11. 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 realized. The Company recognized no material adjustment for unrecognized income tax benefits. Through December 31, 2015, 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:

	December 31,	
	2015	2014
Deferred tax assets:		
Net operating losses	$ 20,350,451	$ 16,113,309
Research and development credits	1,814,296	1,640,277
Deferred rent	15,599	17,844
Accrued compensation	438,351	31,060
Stock compensation	1,500,520	1,349,899
Basis difference in tangible and intangible assets	207,157	340,570
Total deferred tax assets	24,326,374	19,492,959
Less valuation allowance	(24,326,374)	(19,492,959)
Net deferred tax asset	$ —	$ —

For the year ended December 31, 2015, the Company increased the valuation allowance by $4.8 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, 2015 the Company had $51.6 million of Federal and Maryland net operating loss ("NOL") carryforwards that will begin to expire in 2031. As of December 31, 2015 the Company had $1.4 million and $0.4 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 and research and development credits that the Company can utilize annually to offset future taxable income or tax liabilities. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the NOL carryforwards are subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, which could be significant, there would be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance. Subsequent ownership changes may further affect the limitation in future years. All of the Company's tax years are currently open to examination by each tax jurisdiction in which the Company is subject to taxation.

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:

	December 31,	
	2015	2014
Federal statutory rate	34.00 %	34.00 %
Permanent differences	(0.02)%	(0.02)%
Warrants	4.26 %	4.80 %
State taxes	5.12 %	7.22 %
Research and development credit	2.69 %	2.75 %
Other	0.03 %	0.15 %
Change in valuation allowance	(46.08)%	(48.90)%
Effective income tax rate	0.00 %	0.00 %

12. Commitments and Contingencies

Offer Letters

The Company has entered into offer letters with certain of its executives. The letters provide for, among other items, salary, bonus and severance payments.

Resignation of Former Chief Executive Officer

On December 17, 2015, the Company's President and former Chief Executive Officer ("CEO") resigned, which included his resignation as a member of the board of directors of the Company, in each case effective December 31, 2015. The Company entered into a separation agreement pursuant to which the Company agreed to pay the former CEO severance payments in accordance with his existing employment agreement totaling $527,500 and the maintenance of health benefits for a period of up to one year from the separation date. The separation agreement also provided for the modification of existing stock option grants such that all unvested portions of existing stock option grants were immediately vested and all existing stock option grants became exercisable for up to 90 days from the date of separation as in accordance with the terms of the original grants. The former CEO is subject to restrictive covenants, including non-competition and non-solicitation provisions. The severance payments and stock-based compensation related to the modification of existing grants was included as part of general and administrative expenses for the year ended December 31, 2015 in the accompanying statement of operations.

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. Rent expense amounted to approximately $190,000 and $192,000 for the years ended December 31, 2015 and 2014, respectively. Pursuant to the terms of such lease, the Company's future lease obligation is as follows:

Year ending December 31,	
2016	$ 151,068
2017	154,845
2018	158,716
	$ 464,629

Obligations to Contract Research Organizations and External Service Providers

The Company has entered into agreements with contract research organizations and other external service providers for services, primarily in connection with the clinical trials and development of the Company's product candidates. The Company was contractually obligated for up to approximately $3.6 million of future services under these agreements as of December 31, 2015. The Company's actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

13. Selected Quarterly Financial Data (Unaudited)

The following table sets forth certain unaudited quarterly financial data for 2015 and 2014. This unaudited information has been prepared on the same basis as the audited information included elsewhere in this Annual Report on Form 10-K and includes all adjustments necessary to present fairly the information set forth therein.

	Three Months Ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 1,723	$ 1,875	$ 1,238	$ 1,751
General and administrative	761	1,016	722	1,924
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	(535)	198	1,465	185
Interest income (expense), net	(219)	(219)	(197)	(158)
Net loss	$ (3,238)	$ (2,912)	$ (692)	$ (3,648)
Net loss attributable to common stockholders	$ (3,238)	$ (2,912)	$ (692)	$ (3,648)
Net loss per share of common stock, basic and diluted	$ (4.98)	$ (4.48)	$ (1.06)	$ (0.53)

	Three Months Ended			
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 2,750	$ 2,861	$ 4,371	$ 2,259
General and administrative	879	794	1,627	1,575
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	—	386	348	1,532
Interest income (expense), net	0	(795)	(190)	(221)
Net loss	$ (3,629)	$ (4,064)	$ (5,840)	$ (2,523)
Net income (loss) attributable to common stockholders	$ (3,629)	$ (4,064)	$ 6,695	$ (2,523)
Earnings (net loss) per share of common stock, basic and diluted	$ (5.71)	$ (6.39)	$ 10.35	$ (3.88)

EXHIBIT INDEX

The following is a list of exhibits filed as part of this Annual Report on Form 10-K. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of Cerecor Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on October 20, 2015).
3.2	Amended and Restated Bylaws of Cerecor Inc. (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the Current Report on Form 8-K filed on October 20, 2015).
4.1	Second Amended and Restated Investors' Rights Agreement, dated as of July 11, 2014 (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.2	Form of Warrant to Purchase Shares of Common Stock issued in connection with the sale of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.3	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 (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.4	Form of Warrant to Purchase Shares of Common Stock, issued to CIFCO International Group and its affiliate (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.5	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 (incorporated by reference to Exhibit 4.6 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.6	Warrant Agreement, dated as of August 19, 2014, issued to Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.7	Form of Unit Purchase Option (incorporated by reference to Annex IV of Exhibit 1.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
4.9	Form of Class A Warrant Agreement (incorporated by reference to Exhibit 4.9 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.10	Specimen Class A Warrant Certificate (incorporated by reference to Exhibit 4.10 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.11	Form of Class B Warrant Agreement (incorporated by reference to Exhibit 4.11 to the Registration Statement on Form S-1 filed on October 13, 2015).
4.12	Specimen Class B Warrant Certificate (incorporated by reference to Exhibit 4.12 to the Registration Statement on Form S-1 filed on October 13, 2015).

4.13	Specimen Unit Certificate (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-1 filed on October 13, 2015).
10.1 #	Exclusive Patent and Know-How License Agreement, effective as of March 19, 2013, by and between Essex Chemie AG and Cerecor Inc. (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.2 #	Exclusive Patent and Know-How License Agreement, effective as of March 19, 2013, by and between Essex Chemie AG and Cerecor Inc. (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.3 #	Exclusive Patent and Know-How License Agreement, effective as of February 18, 2015, by and between Eli Lilly and Company and Cerecor Inc. (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.4 +	Cerecor Inc. 2011 Stock Incentive Plan, as amended, including forms of Incentive Stock Option Agreements and Nonqualified Stock Option Agreements thereunder (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.5 +	Cerecor Inc. 2015 Omnibus Incentive Plan, including form of Nonqualified Stock Option Agreements thereunder (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 filed on September 8, 2015).
10.6 +	Offer Letter Agreement by and between Cerecor Inc. and John Kaiser, dated as of September 12, 2012 (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.7 +	Offer Letter Agreement by and between Cerecor Inc. and James Vornov, dated as of September 18, 2012 (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.8 +	Offer Letter Agreement by and between Cerecor Inc. and Ronald Marcus, dated as of May 5, 2015 (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.9 +	Offer Letter Agreement by and between Cerecor Inc. and Uli Hacksell, dated as of May 20, 2015 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.10 +	Offer Letter Agreement by and between Cerecor Inc. and Mariam Morris, effective as of August 24, 2015 (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 filed on September 8, 2015).
10.11 +	Employment Agreement by and between Cerecor Inc. and Uli Hacksell, effective January 1, 2016.
10.12 +	Separation Agreement by and between Cerecor Inc. and Blake Paterson, effective January 9, 2016.
10.13 +	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 filed on September 8, 2015).

10.14	List of current directors with a Director Indemnification Agreement in the form provided as Exhibit 10.12 (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 filed on September 8, 2015).
10.15	Lease Agreement by and between Cerecor Inc. and PDL Pratt Associates, LLC, dated as of August 8, 2013 (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.16	Loan and Security Agreement, dated as of August 19, 2014, by and between Cerecor Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1 filed on June 12, 2015).
10.17	Non-Employee Director Compensation Plan.
21.1	List of Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.
31.1 *	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2 *	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 *	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

+ 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.

* These certifications are being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 10.11

EXECUTIVE EMPLOYMENT AGREEMENT

This **EMPLOYMENT AGREEMENT** (the "Agreement") is entered into effective January 1, 2016 (the "Effective Date"), by and between Uli Hacksell (the "Executive") and Cerecor Inc., a Delaware corporation (the "Company").

The Company desires to employ the Executive and, in connection therewith, to compensate the Executive for Executive's personal services to the Company; and

The Executive wishes to be employed by the Company and to provide personal services to the Company in return for certain compensation.

Accordingly, in consideration of the mutual promises and covenants contained herein, the parties agree to the following:

1. Position and Duties. During Executive's employment with the Company pursuant to this Agreement (the "Employment Term"), Executive shall serve as the Chief Executive Officer of the Company. As of the Effective Date, Executive also serves as Chairman of the Company's Board of Directors (the "Board") and may continue to do so at the election of the Board. In his capacity as Chief Executive Officer, Executive shall have such duties, authorities and responsibilities as are commensurate with his position as the Board shall designate from time to time. Executive shall be based in Baltimore, Maryland and shall report to the Board. During the Employment Term, Executive shall devote all of his business time, energy and skill and his best efforts to the performance of his duties with the Company; provided, that (i) Executive may be a passive investor or perform non-operational, advisory roles (e.g. advisory boards) provided that such activity does not interfere with his duties under this Agreement, and (ii) Executive may engage in limited advisory relationships with companies that are not in competitive markets and civic and not-for-profit activities so long as such activities do not interfere with the performance of his duties hereunder.

2. Base Salary. Beginning on the Effective Date, the Company agrees to pay Executive a base salary at an annual rate of $500,000, payable subject to standard federal and state payroll withholding requirements in accordance with the regular payroll practices of the Company (the "Base Salary") subject to review and adjustment by the Board from time to time.

3. Annual Bonus. During the Employment Term, Executive shall be eligible for a discretionary annual cash bonus of up to 45% of Base Salary ("***Target Amount***"). Any bonus awarded will be in an amount of up to 45% of Base Salary as determined by the Board and may consist of cash and/or grants of equity in the Company, subject to the results of operations and financial condition of the Company and Executive's individual performance. Whether or not Executive earns any bonus will be dependent upon (a) Executive's continuous performance of services to the Company through the date any bonus is paid; and (b) the actual achievement of any applicable performance targets and goals by Executive (to the extent that goals are established by the Board after consultation with Executive) . The Board will determine in its sole discretion the extent to which Executive and the Company have achieved any performance goals upon which the bonus is based and the amount of the bonus, which could be below the Target Amount (and may be zero). The Executive's eligibility for a bonus is subject to change in the discretion of the Board

(or any authorized committee thereof). The annual period over which performance is measured for purposes of this bonus is January 1 through December 31. To the extent the Annual Bonus consists of cash, such amount will be payable subject to standard federal and state payroll withholding requirements on or before March 15 of the year following the year for which it is earned.

4. Stock Option. Subject to approval of the Company's Board, the Company anticipates granting Executive the option to purchase 360,459 shares of the Company's common stock, subject to the terms of the Company's 2015 Omnibus Incentive Compensation Plan and standard form of stock option agreement (the "Option"). The Option shall be an incentive stock option to the extent permissible under Section 422 of the Internal Revenue Code of 1986, as amended, and will have an exercise price per share equal to the fair market value of a share of common stock of the Company as of the date of grant. Subject to Executive's continued employment with the Company, the Executive's right to exercise the Option shall accrue as follows: one third of the shares subject to the Option (33 1/3%) shall vest on the first anniversary of the Effective Date, and the remaining 66 2/3% of the shares subject to the Option will then vest in equal monthly installments on each monthly anniversary date of the first vesting date over the following 24 months.

5. Employee Benefits.

(a) **Benefit Plans.** Executive shall be eligible to participate in employee benefit plans of the Company on the same basis as similarly situated employees. The Company may modify or terminate any employee benefit plan at any time.

(b) **Vacation.** Executive shall be eligible for paid vacation in accordance with the Company's vacation policy in effect from time to time.

(c) **General Expense Reimbursement.** Upon presentation of appropriate documentation, Executive shall be reimbursed in accordance with the Company's expense reimbursement policy, for reasonable business expenses. For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A of the Code: (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(d) **Travel and Lodging Expenses.** The Company will reimburse Executive for reasonable living quarters in the Baltimore, Maryland area, as well as related reasonable coach travel from his home in Florida to the Baltimore/Washington DC area, in a combined maximum gross amount of $5,000 per month (less required withholding and/or deductions required by the applicable law, if any) ("***Travel and Lodging Expenses***"). The Company shall reimburse such Travel and Lodging Expenses within thirty (30) days of receipt of an invoice or other documentation that complies with Company policies, provided that Executive submits such receipts and other documentation within sixty (60) days following the date such Travel and Lodging Expenses are incurred. For the avoidance of doubt, to the extent that any reimbursements payable to Executive pursuant to this Section 5(d) are subject to the provisions of Section 409A

of the Code: (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

6. Termination of Employment. The parties acknowledge that Executive's employment relationship with the Company is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause. The provisions in this Section govern the amount of compensation, if any, to be provided to Executive upon termination of employment and do not alter this at-will status.

(a) Death or Disability. Executive's employment shall immediately terminate on the date of his death or upon ten (10) days' prior written notice by the Company for Disability. Termination of Executive's employment based on "Disability" shall mean termination because Executive is unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for 180 days in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. Upon Executive's termination due to death or Disability, Executive (or his estate or legal representative, if applicable) shall be entitled to the following payments and benefits: (i) any unpaid Base Salary through the date of termination any accrued but unused vacation time paid on the Company's next regular payroll date, or earlier if required by law; (ii) reimbursement for any unreimbursed, reasonable, documented business expenses incurred through the date of termination and in accordance with Company policy, payable within thirty (30) days following such termination of employment, (iii) all other vested payments, benefits or fringe benefits to which Executive is entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant (collectively, Sections 6(a)(i), 6(a)(ii) and 6(a)(iii) shall be hereafter referred to as the " Accrued Benefits") and (iii) subject to Executive's, or, in the event of death, Executive's personal representative's compliance with the obligations in Sections 7, 8, and 9 hereof, an amount equal to the average of the annual full-year cash bonuses Executive received from the Company for the three (3) completed calendar years prior to termination (or fewer full year periods if the employment term is less than three (3) years, pro rated for the portion of the year in which such termination occurred (the "Pro Rata Average Bonus "), subject to standard payroll deductions and withholdings, payable in twelve (12) equal monthly installments following such termination; provided, that the first payment shall be made on the first payroll period after the sixtieth (60 th) day following such termination and shall include payment of any amounts that would otherwise be due prior thereto.

(b) For Cause. Executive's employment with the Company shall terminate immediately upon written notice by the Company for Cause. "Cause" shall mean: (i) Executive's willful misconduct or gross negligence in the performance of his duties to the Company that, if capable of cure, is not cured within thirty (30) days of Executive's receipt of written notice from the Company; (ii) Executive's failure to perform his duties to the Company or to follow the lawful directives of the Board (other than as a result of death or a physical or mental incapacity) that, if capable of cure, is not cured within thirty (30) days of Executive's receipt of written notice from

the Company; (iii) any conduct which constitutes a felony under applicable law; (iv) any act of theft, fraud, malfeasance or dishonesty in connection with the performance of Executive's duties to the Company; or; (v) a material breach of this Agreement or any other agreement with the Company, or a material violation of the Company's code of conduct or other written policy that, if capable of cure, is not cured within thirty (30) days of Executive's receipt of written notice from the Company. Upon a termination for Cause, Executive will not receive severance payments, or any other severance compensation or benefit, except that, consistent with the Company's standard payroll policies, the Company shall provide to Executive the Accrued Benefits.

(c) Without Cause. Executive's employment may be terminated by the Company without Cause (other than for death or Disability) immediately upon written notice by the Company. Upon a termination without Cause, the Company shall pay to Executive the Accrued Benefits, paid according to the Company's standard payroll policies. Subject to Executive's compliance with the obligations in Sections 7, 8, and 9 hereof, Executive will be eligible for the following severance benefits:

(i) The Company (1) shall provide continued payment of Executive's Base Salary as in effect immediately prior to Executive's termination for twelve (12) months following such termination and (2) shall pay Executive's Pro Rata Average Bonus, provided, that such payments pursuant to clauses (1) and (2) will be subject to standard payroll deductions and withholdings, will be paid in twelve (12) equal monthly installments following the termination date, and the first payment pursuant to these clauses (1) and (2) shall be made on the Company's first ordinary payroll date that occurs at least sixty (60) days following the termination date and shall include payment of any amounts that would otherwise be due prior thereto;

(ii) If Executive timely elects continued coverage under COBRA for himself and his covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Executive's and his covered dependents' health insurance coverage in effect for himself (and his covered dependents) on the termination date until the earliest of: (x) the first anniversary of Executive's termination; (y) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (z) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (x)-(z), (the "COBRA Payment Period"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Executive's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding, for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive Executive of his rights under COBRA or ERISA for benefits under plans and policies arising under his employment by the Company; and

(iii) Executive's Restricted Stock Award and any stock option or stock award granted during the Employment Term shall vest in full.

(d) For Good Reason. Executive's employment shall terminate upon Executive's written notice to the Company of a termination for Good Reason. "Good Reason" for resignation shall mean the occurrence of any of the following without the Executive's prior written consent: (i) a reduction in Executive's title, reporting relationship or the assignment to Executive of any duties or responsibilities which result in the material diminution of Executive's then current position; provided, however, that the acquisition of the Company and subsequent conversion of the Company to a division or unit of the acquiring company will not by itself result in a diminution of Executive's position; (ii) a material reduction in Executive's base salary, which the parties agree is a reduction of at least 10% of Executive's base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees); (iii) relocation of Executive's primary office to a location that increases Executive's commute by more than thirty-five (35) miles from the location at which Executive worked immediately prior to such change; or (iv) a material breach by the Company of the terms of this Agreement. Notwithstanding the foregoing, any actions taken by the Company to accommodate a disability of the Executive or pursuant to the Family and Medical Leave Act shall not constitute Good Reason for purposes of this Agreement. Upon a termination for Good Reason, Executive shall be eligible for the severance benefits described in Section 6(c) above subject to compliance with Section 7, 8 and 9 below.

(e) Other Obligations. Upon any termination of Executive's employment with the Company, Executive shall promptly resign from the Board and any other position as an officer, director or fiduciary of any Company-related entity. Payments and benefits provided in this Section 6 shall be in lieu of any termination or severance payments or benefits for which Executive may be eligible under any of the plans, policies or programs of the Company or under the Worker Adjustment Retraining Notification Act of 1988 or any similar state statute or regulation. The damages caused by the termination of Executive's employment without Cause or for Good Reason would be difficult to ascertain; therefore, the severance for which Executive is eligible pursuant to Section 6 is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

7. Release. Any payments and benefits provided under this Agreement, including accelerated vesting of the Restricted Stock Award, beyond the Accrued Benefits, shall only be payable if Executive executes and delivers to the Company and does not revoke a separation agreement in a form reasonably satisfactory to the Company containing a full, general release of claims in favor of the Company. Such release must be executed and delivered (and no longer subject to revocation, if applicable) within sixty (60) days following termination. The Company shall deliver to Executive such release within seven (7) days after termination.

8. Restrictive Covenants.

(a) Confidentiality. Executive agrees that Executive shall not, directly or indirectly, use, make available, sell, disclose or otherwise communicate to any person, either during Executive's employment or at any time thereafter, any business and technical information or trade secrets, nonpublic, proprietary or confidential information, knowledge or data relating to the Company, any of its subsidiaries, affiliated companies or businesses, which shall have been obtained by Executive during his employment by the Company (or any predecessor). The foregoing shall not apply to information that (A) was known to the public prior to its disclosure to Executive or (B) Executive is required to disclose by applicable law, regulation or legal process

(provided that Executive provides the Company with prior notice of the contemplated disclosure and cooperate with the Company at its expense in seeking a protective order or other appropriate protection of such information). The terms and conditions of this Agreement shall remain strictly confidential, and Executive hereby agrees not to disclose the terms and conditions hereof to any person or entity, other than immediate family members, legal advisors or personal tax or financial advisors, or prospective future employers solely for the purpose of disclosing the limitations on Executive's conduct imposed by the provisions of this Section 8.

(b) Non-Competition. Executive acknowledges that he performs services of a unique nature for the Company that are irreplaceable, and that his performance of such services to a competing business will result in irreparable harm to the Company. Accordingly, during the Executive's employment hereunder and for a period of one (1) year thereafter, Executive agrees that he will not, directly or indirectly, solicit, perform, or provide Conflicting Services (whether as an employee, consultant, independent contractor or otherwise, and whether or not for compensation) in any locale of any country in which the Company conducts business (in the case of the one (1) year period following termination, in any locale of a country in which the Company was conducting business in the one (1) year period prior to the termination date). For purposes of this Agreement, "Conflicting Services" means any product, service, or process or the research and development thereof, of any person or organization other than the Company that directly competes with a product, service, or process, including the research and development thereof, of the Company with which Executive worked directly or indirectly during his employment by the Company or about which he acquired proprietary information during his employment by the Company. Notwithstanding the foregoing, nothing herein shall prohibit Executive from being a passive owner of not more than two percent (2%) of the equity securities of a publicly traded corporation engaged in a business that is in competition with the Company or any of its subsidiaries or affiliates.

(c) Non-Solicitation; Non-Interference.

(i) During Executive's employment with the Company and for a period of one (1) year thereafter, Executive agrees that he shall not, directly or indirectly, individually or on behalf of any other person, firm, corporation or other entity, solicit, aid or induce any customer of the Company or any of its subsidiaries or affiliates to purchase goods or services then sold by the Company or any of its subsidiaries or affiliates from another person, firm, corporation or other entity or assist or aid any other persons or entity in identifying or soliciting any such customer.

(ii) During Executive's employment with the Company and for a period of one (1) year thereafter, Executive agrees that he shall not, directly or indirectly, individually or on behalf of any other person, firm, corporation or other entity, (A) solicit, aid or induce any employee, representative or agent of the Company or any of its subsidiaries or affiliates to leave such employment or retention or to accept employment with or render services to or with any other person, firm, corporation or other entity unaffiliated with the Company or directly hire or retain any such employee, representative or agent, or take any action to materially assist or aid any other person, firm, corporation or other entity in identifying, hiring or soliciting any such employee, representative or agent, or (B) interfere, or aid or induce any other person or entity in interfering, with the relationship between the Company or any of its subsidiaries or affiliates and any of their respective vendors, joint venturers or licensors. An employee, representative or agent shall be

deemed covered by this Section 8(c) if such person was employed or retained during anytime within six (6) months prior to, or after, Executive's termination of employment.

(d) Non-Disparagement. Executive agrees not to make negative comments or otherwise disparage the Company or its officers, directors, employees, shareholders, agents or products, in any manner likely to be harmful to them or their business, business reputation or personal reputation. The foregoing shall not be violated by truthful statements in response to legal process, required governmental testimony or filings, or administrative or arbitral proceedings (including, without limitation, depositions in connection with such proceedings). Notwithstanding the foregoing, nothing in this Agreement shall limit Executive's right to discuss his employment with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, other federal government agency or similar state or local agency or to discuss the terms and conditions of his employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

(e) Inventions.

(i) Executive acknowledges and agrees that all ideas, methods, inventions, discoveries, improvements, work products or developments ("Inventions"), whether patentable or unpatentable, (A) that relate to Executive's work with the Company, made or conceived by Executive, solely or jointly with others, during the Employment Term, or (B) suggested by any work that Executive performs in connection with the Company, either while performing his duties with the Company or on his own time, but only insofar as the Inventions are related to Executive's work as an employee or other service provider to the Company, shall belong exclusively to the Company (or its designee), whether or not patent applications are filed thereon. Executive will keep full and complete written records (the "Records"), in the manner prescribed by the Company, of all Inventions, and will promptly disclose all Inventions completely and in writing to the Company. The Records shall be the sole and exclusive property of the Company, and Executive will surrender them upon the termination of the Employment Term, or upon the Company's request. Executive will assign to the Company the Inventions and all patents that may issue thereon in any and all countries, whether during or subsequent to the Employment Term, together with the right to file, in Executive's name or in the name of the Company (or its designee), applications for patents and equivalent rights (the "Applications"). Executive will, at any time during and subsequent to the Employment Term, make such applications, sign such papers, take all rightful oaths, and perform all acts as may be requested from time to time by the Company with respect to the Inventions. Executive will also execute assignments to the Company (or its designee) of the Applications, and give the Company and its attorneys all reasonable assistance (including the giving of testimony) to obtain the Inventions for its benefit, all without additional compensation to Executive from the Company, but entirely at the Company's expense.

(ii) This Agreement will not be deemed to require assignment of any Invention that Executive develops entirely on his own time without using the Company's equipment, supplies, facilities, trade secrets, or proprietary information, except for those Inventions that either (i) relate to the Company's actual or anticipated business, research or development, or (ii) result from or are connected with work performed by Executive for the Company. In addition, this Agreement does not apply to any Invention which qualifies fully for protection from assignment to the Company under any specifically applicable state law, regulation, rule, or public policy or

which otherwise qualifies as a nonassignable Invention under Del. Code Ann., Title 19, § 805. Executive acknowledged that he has reviewed the notification on Exhibit A (Limited Exclusion Notification) and agrees that his signature acknowledges receipt of the notification.

(iii) In addition, the Inventions will be deemed Work for Hire, as such term is defined under the copyright laws of the United States, on behalf of the Company and Executive agrees that the Company will be the sole owner of the Inventions, and all underlying rights therein, in all media now known or hereinafter devised, throughout the universe and in perpetuity without any further obligations to Executive. If the Inventions, or any portion thereof, are deemed not to be Work for Hire, Executive hereby irrevocably conveys, transfers and assigns to the Company, all rights, in all media now known or hereinafter devised, throughout the universe and in perpetuity, in and to the Inventions, including, without limitation, all of Executive's right, title and interest in the copyrights (and all renewals, revivals and extensions thereof) to the Inventions, including, without limitation, all rights of any kind or any nature now or hereafter recognized, including without limitation, the unrestricted right to make modifications, adaptations and revisions to the Inventions, to exploit and allow others to exploit the Inventions and all rights to sue at law or in equity for any infringement, or other unauthorized use or conduct in derogation of the Inventions, known or unknown, prior to the date hereof, including, without limitation, the right to receive all proceeds and damages therefrom. In addition, Executive hereby waives any so-called "moral rights" with respect to the Inventions. Executive hereby waives any and all currently existing and future monetary rights in and to the Inventions and all patents that may issue thereon, including, without limitation, any rights that would otherwise accrue to Executive's benefit by virtue of Executive being an employee of or other service provider to the Company.

(f) Return of Company Property. On the date of Executive's termination of employment with the Company for any reason (or at any time prior thereto at the Company's request), Executive shall return all property belonging to the Company or its affiliates (including, but not limited to, any Company-provided laptops, computers, cell phones, wireless electronic mail devices or other equipment, or documents and property belonging to the Company).

(g) Reasonableness of Restrictions.

(i) Executive agrees that he has read this Section 8 and understands it. Executive agrees that this Section 8 does not prevent him from earning a living or pursuing his career. Executive agrees that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Company's legitimate business interests. Executive represents and agrees that he is entering into this Agreement freely and with knowledge of its contents with the intent to be bound by the Agreement and the restrictions contained in it.

(ii) In the event that a court finds this Section 8, or any of its restrictions, to be ambiguous, unenforceable, or invalid, Executive and the Company agree that the court will read the Agreement as a whole and interpret the restriction(s) at issue to be enforceable and valid to the maximum extent allowed by law.

(iii) If the court declines to enforce this Section 8 in the manner provided in subsection Section 8(g)(ii), Executive and the Company agree that this Agreement will be

automatically modified to provide the Company with the maximum protection of its business interests allowed by law and Executive agrees to be bound by this Section 8 as modified.

(iv) If after applying the provisions of subsections Section 8(g)(ii)-(iii), a court still decides that this Section 8 or any of its restrictions is unenforceable for lack of reasonable geographic limitation and the restriction(s) cannot otherwise be enforced, the parties hereby agree that the fifty (50) mile radius from any location at which Executive worked for the Company on either a regular or occasional basis during the one (1) year immediately preceding termination of his employment with the Company shall be the geographic limitation relevant to the contested restriction.

(h) Tolling. In the event of any violation of the provisions of this Section 8, Executive acknowledges and agrees that the post-termination restrictions contained in this Section 8 shall be extended by a period of time equal to the period of such violation, it being the intention of the parties hereto that the running of the applicable post-termination restriction period shall be tolled during any period of such violation.

(i) Survival of Provisions. The obligations contained in Sections 8 and 9 hereof shall survive the termination or expiration of the Employment Term and Executive's employment with the Company and shall be fully enforceable thereafter.

9. Cooperation. Upon the receipt of reasonable notice from the Company (including outside counsel), Executive agrees that while employed by the Company and thereafter, Executive will respond and provide information with regard to matters in which he has knowledge as a result of his employment with the Company, and will provide reasonable assistance to the Company, its affiliates and their respective representatives in defense of any claims that may be made against the Company or its affiliates, and will assist the Company and its affiliates in the prosecution of any claims that may be made by the Company or its affiliates, to the extent that such claims may relate to the period of Executive's employment with the Company. Executive agrees to promptly inform the Company if he becomes aware of any lawsuits involving such claims that may be filed or threatened against the Company or its affiliates. Executive also agrees to promptly inform the Company (to the extent that he is legally permitted to do so) if he is asked to assist in any investigation of the Company or its affiliates (or their actions), regardless of whether a lawsuit or other proceeding has then been filed against the Company or its affiliates with respect to such investigation, and shall not do so unless legally required. Upon presentation of appropriate documentation, the Company shall pay or reimburse Executive for all reasonable out-of-pocket travel, duplicating or telephonic expenses incurred by Executive in complying with this Section 11.

10. Equitable Relief and Other Remedies. Executive acknowledges and agrees that the Company's remedies at law for a breach or threatened breach of any of the provisions of Section 8 or Section 9 hereof would be inadequate and, in recognition of this fact, Executive agrees that, in the event of such a breach or threatened breach, in addition to any remedies at law, the Company, without posting any bond, shall be entitled to equitable relief in the form of specific performance, a temporary restraining order, a temporary or permanent injunction or any other equitable remedy which may then be available. In the event of a violation by Executive of Section 8 or Section 9 hereof, any severance being paid to Executive pursuant to this Agreement or otherwise shall

immediately cease, and any severance previously paid to Executive (other than $1,000) shall be immediately repaid to the Company.

11. No Assignments. This Agreement is personal to each of the parties hereto. Except as provided in this Section 11, no party may assign or delegate any rights or obligations hereunder without first obtaining the written consent of the other party hereto except that the Company may assign this Agreement to any successor to all or substantially all of the business and/or assets of the Company.

12. Notice. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by electronic mail, telex or confirmed facsimile if sent during normal business hours of the recipient, and if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Employee at Employee's address as listed on the Company payroll or to the Employee's Company-issued email address, or at such other address as the Company or the Employee may designate by ten (10) days advance written notice to the other.

13. Severability. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof.

14. Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument.

15. Governing Law; Disputes. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Delaware without regard to the choice of law principles thereof that would result in the application of the laws of any other jurisdiction. Executive and the Company agree that any action or proceeding to enforce or arising out of this Agreement may be commenced in the state appellate courts of New Castle County, Wilmington, Delaware or the United States District Court for the District of Delaware in Wilmington, Delaware. Executive and the Company consent to such jurisdiction, agree that venue will be proper in such courts and waive any objections upon "*forum non conveniens*."

16. Miscellaneous. No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by Executive and such officer or director as may be designated by the Board. No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time. This Agreement together with all exhibits hereto sets forth the entire agreement of the parties hereto in respect of the subject matter contained herein and supersedes any and all prior agreements or understandings between Executive and the Company with respect to the subject matter hereof. No agreements or

representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by either party which are not expressly set forth in this Agreement.

17. Representations. Executive represents and warrants to the Company that (a) Executive has the legal right to enter into this Agreement and to perform all of the obligations on Executive's part to be performed hereunder in accordance with its terms, and (b) Executive is not a party to any agreement or understanding, written or oral, and is not subject to any restriction, which, in either case, could prevent Executive from entering into this Agreement or performing all of his duties and obligations hereunder.

18. Tax Withholding. The Company may withhold from any and all amounts payable under this Agreement such federal, state and local taxes as may be required to be withheld pursuant to any applicable law or regulation.

19. Code Section 409A.

(a) The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from, Internal Revenue Code Section 409A and the regulations and guidance promulgated thereunder (collectively "Code Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith. In no event whatsoever shall the Company be liable for any additional tax, interest or penalty that may be imposed on Executive by Code Section 409A or any damages for failing to comply with Code Section 409A.

(b) A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment that are considered "non-qualified deferred compensation" under Code Section 409A unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." If Executive is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment that is considered non-qualified deferred compensation under Code Section 409A payable on account of a "separation from service," such payment or benefit shall be made or provided at the date which is the earlier of (A) the expiration of the six (6)-month period measured from the date of Executive's "separation from service", and (B) the date of Executive's death (the "Delay Period"). Upon the expiration of the Delay Period, all payments and benefits delayed pursuant to this Section 19 (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid or reimbursed to Executive in a lump sum and any remaining payments and benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(c) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits

to be provided, in any other taxable year, provided that the foregoing clause (ii) shall not be violated with regard to expenses reimbursed under any arrangement covered by Internal Revenue Code Section 105(b) solely because such expenses are subject to a limit related to the period the arrangement is in effect and (iii) such payments shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense was incurred.

(d) For purposes of Code Section 409A, Executive's right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. In no event may Executive, directly or indirectly, designate the calendar year of any payment to be made under this Agreement that is considered non-qualified deferred compensation.

IN WITNESS WHEREOF, the parties have duly executed this Agreement as of the date first above written.

CERECOR INC.

By: /s/ Mariam E. Morris
Mariam E. Morris
Chief Financial Officer

EXECUTIVE

/s/ Uli Hacksell
Uli Hacksell

EXHIBIT A

LIMITED EXCLUSION NOTIFICATION

THIS IS TO NOTIFY you in accordance with Del. Code Ann., Title 19, § 805 that the Agreement between you and Company does not require you to assign or offer to assign to Company any Invention that you develop entirely on your own time without using Company's equipment, supplies, facilities or trade secret information, except for those Inventions that either:

a. Relate to Company's business, or actual or demonstrably anticipated research or development; or

b. Result from any work performed by you for Company.

To the extent a provision in the foregoing Agreement purports to require you to assign an Invention otherwise excluded from the preceding paragraph, the provision is against the public policy of this state and is unenforceable.

Exhibit 10.12

December 23, 2015

Blake M. Paterson

Re: Separation Agreement

Dear Blake:

This letter sets forth the substance of the separation agreement (the "Agreement") which Cerecor Inc. (the "Company") is offering to you to aid in your employment transition.

1. Separation. The Company has accepted your resignation from employment with the Company effective December 31, 2015 (the "Separation Date"). The letter agreement between you and the Company dated April 28, 2011 (the "Employment Agreement"), requires you to resign from the Company's Board of Directors and as an officer of the Company when your employment terminates for any reason. Therefor you agree to execute and deliver to Uli Hacksell the resignation letter attached as Exhibit A (the "Resignation Letter").

2. Accrued Salary and Vacation. On the next regular payroll date following the Separation Date, the Company will pay you all accrued salary, all accrued and unused vacation earned through the Separation Date, and an annual bonus for the year ending on December 31, 2015, in the amount of $207,500.00, each subject to standard payroll deductions and withholdings. You will receive these payments regardless of whether or not you sign this Agreement.

3. Severance Benefits. If you execute this Agreement on or after December 31, 2015 and do not revoke it, and execute and deliver the Resignation Letter attached as Exhibit A, the Company will provide you with the following "Severance Benefits":

a . The Company will make severance payments to you in the form of continuation of your base salary in effect on the Separation Date (which the parties agree is currently $415,000.00 on an annualized basis) for twelve (12) months following the Separation Date. These payments will be subject to standard payroll deductions and withholdings and will be made on the Company's ordinary payroll dates, beginning with the first such date which occurs at least sixty (60) days following the Separation Date ("Initial Severance Payment Date"), provided the Company has received the executed Agreement from you on or before that date. The first payment under this clause shall be equal to the aggregate amount of payments that the Company would have paid through the Initial Severance Payment Date had such payments commenced on the Separation Date, with the balance of the payments paid thereafter on the schedule described above.

b . The Company will pay you $112,500.00. This additional payment will be subject to standard payroll deductions and withholdings and will be paid in twelve (12) equal

monthly installments following the Separation Date, with the first payment on the Company's first ordinary payroll date that occurs at least six (6) months following the Separation Date (the "Six Month Payment Date"), provided the Company has received the executed Agreement from you in accordance with the terms of this Agreement. The first payment under this clause shall be equal to the aggregate amount of payments that the Company would have paid through the Six Month Payment Date had such payments commenced on the Separation Date, with the balance of the payments paid thereafter on the schedule described above.

c . If you timely elect continued coverage under COBRA for yourself and your covered dependents under the Company's group health plans following the Separation Date, then the Company will pay the COBRA premiums necessary to continue your health insurance coverage in effect for yourself and your covered dependents on the Separation Date until the earliest of (A) the first anniversary of the Separation Date, **(**B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) the date when you become eligible for substantially equivalent health insurance coverage (such period from the Separation Date through the earliest of (A) through (C), the "COBRA Payment Period." Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on your behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company will pay you on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding (such amount, the "Special Severance Payment"), for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive you of your rights under COBRA or ERISA for benefits under plans and policies arising under your employment by the Company. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the COBRA Payment Period, you must immediately notify the Company of such event, and all payments and obligations under this clause will cease.

4. Benefit Plans.

If you are currently participating in the Company's group health insurance plans, your participation as an employee will end on December 31, 2015. Thereafter, to the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense, with the option for certain COBRA payments to be made by the Company as described in Section 3 above. Later, you may be able to convert to an individual policy through the provider of the Company's health insurance, if you wish.

Your participation in Employer-Sponsored Group Life Insurance and Short and Long Term Disability Insurance will cease as of December 31, 2015.

Deductions for the 401(k) Plan will end with your last regular paycheck. You will receive information by mail concerning 401(k) plan rollover procedures should you be a participant in this program.

You have the right to continue your current Health Care Spending Account if you are participating in this program. Enclosed as Exhibit B is the information concerning how to continue this benefit. Dependent Care Spending Accounts can not be continued. Your last full Spending Account payroll deductions will be processed in the December 31, 2015 pay period. Unless you elect to continue your Health Care Spending Account, you will only be eligible to claim expenses that you incurred prior to December 31, 2015.

5. Stock Options. On a post-split basis, you were granted three separate options to purchase shares of the Company's common stock (each, an "Option") in the share amounts of 107,142 shares (granted May 8, 2012, pursuant to the Company's 2011 Stock Incentive Plan (the "2011 Plan")), 54,353 shares (granted July 10, 2014, pursuant to the 2011 Plan), and 160,000 shares (granted on or about October 20, 2015 through Board action taken on September 2, 2015, pursuant to the 2015 Omnibus Incentive Compensation Plan (the "2015 Plan")). For the grants made on May 8, 2012 and July 10, 2014, all shares subject to such Options are fully vested as of the Separation Date in accordance with the terms of the stock option agreements governing such grants. If you timely return and do not revoke this fully signed Agreement to the Company, then (i) the vesting of the Option granted to you on or about October 20, 2015 will be fully accelerated such that 100% of the shares subject to such Option shall be exercisable by you effective as of the Separation Date and (ii) notwithstanding anything to the contrary in the 2011 Plan, the 2015 Plan, the option grant notices, and the stock option agreements entered into by you and the Company and any other documents between you and the Company setting forth the terms of your Options (the "Option Documents"), your Options will be amended such that you may exercise any vested Options on or before the expiration of the applicable term set forth in the Option Documents governing the applicable Option. You and the Company hereby consent to the modification and amendment of the terms governing your Options and the Option Documents to conform to the provisions of this Agreement, with such modification to occur within thirty (30) days of your execution of the Agreement, provided that you have not revoked your acceptance of the Agreement. Except as modified by this Agreement, all terms, conditions and limitations applicable to the Options will remain in full force and effect pursuant to the applicable Option Documents.

6. Other Compensation or Benefits. You acknowledge and agree that the Severance Benefits set forth herein are in lieu of, and in full satisfaction of, any severance or benefits from the Company to which you may be entitled or eligible, and that the Company's provision of the Severance Benefits under this Agreement supersedes and extinguishes any obligation of the Company to provide you with any severance or benefits under any other agreements. You further acknowledge that, except as expressly provided in this Agreement, you have not earned and will not receive from the Company any additional compensation, severance or benefits after the Separation Date, with the sole exception of any benefit the right to which has vested as of the Separation Date under the express terms of a Company benefit plan document.

7. Expense Reimbursements. You agree that, within ten (10) days of the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek

reimbursement. The Company will reimburse you for reasonable business expenses pursuant to its regular business practice.

8. Return of Company Property. By the Separation Date, you shall return all property belonging to the Company or its affiliates (including, but not limited to, any Company-provided laptops, computers, cell phones, wireless electronic mail devices or other equipment, or documents and property belonging to the Company. Please coordinate return of Company property with Teresa Winhauer . **Receipt of the Severance Benefits described in Section 3 of this Agreement is expressly conditioned upon return of all Company Property.**

9. Proprietary Information and Post-Termination Obligations. Both during and after your employment you acknowledge your continuing obligations under Section 9 of the Employment Agreement (the "Restrictive Covenants"), as modified below, not to use or disclose any confidential or proprietary information of the Company, to refrain from certain solicitation and competitive activities, and not to disparage the Company. A copy of your Employment Agreement, including the Restrictive Covenants, is attached hereto as Exhibit C. If you have any doubts as to the scope of the restrictions in your agreement, you should contact Mariam Morris immediately to assess your compliance. As you know, the Company will enforce its contract rights. Please familiarize yourself with your obligations under the Restrictive Covenants, which are contained in a document that you signed. The parties agree that Section 9(b) of the Employment Agreement will be modified as follows:

Non-Competition. Executive acknowledges that he performs services of a unique nature for the Company that are irreplaceable, and that his performance of such services to a competing business will result in irreparable harm to the Company. Accordingly, during the Executive's employment hereunder and for a period of one (1) year thereafter, Executive agrees that he will not, directly or indirectly, solicit, perform, or provide Conflicting Services (whether as an employee, consultant, independent contractor or otherwise, and whether or not for compensation) in any locale of any country in which the Company conducts business (in the case of the one (1) year period following termination, in any locale of a country in which the Company was conducting business in the one (1) year period prior to the termination date). For purposes of this Agreement, "Conflicting Services" means any product, service, or process or the research and development thereof, of any person or organization other than the Company that directly competes with a product, service, or process, including the research and development thereof, of the Company with which Executive worked directly or indirectly during his employment by the Company or about which he acquired proprietary information during his employment by the Company. Notwithstanding the foregoing, nothing herein shall prohibit Executive from being a passive owner of not more than two percent (2%) of the equity securities of a publicly traded corporation engaged in a business that is in competition with the Company or any of its subsidiaries or affiliates.

10. Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed in any manner whatsoever; *provided, however,* that: (a) you may disclose this Agreement to your immediate family; (b) you may disclose this Agreement in confidence to your attorney, accountant, auditor, tax preparer, and financial advisor; and (c) you may disclose this Agreement insofar as such disclosure may be

required by law. Notwithstanding the foregoing, nothing in this Agreement shall limit your right to discuss your employment with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

11. Cooperation after Termination. During the time that you are receiving payments under this Agreement, you agree that you will respond to reasonable requests, at reasonable times and places, and provide information with regard to matters in which you have knowledge as a result of your employment with the Company, and will provide reasonable assistance to the Company, its affiliates and their respective representatives in defense of any claims that may be made against the Company or its affiliates, and will assist the Company and its affiliates in the prosecution of any claims that may be made by the Company or its affiliates, to the extent that such claims may relate to the period of your employment with the Company. You agree to promptly inform the Company if you become aware of any lawsuits involving such claims that may be filed or threatened against the Company or its affiliates. You also agree to promptly inform the Company (to the extent that you are legally permitted to do so) if you are asked to assist in any investigation of the Company or its affiliates (or their actions), regardless of whether a lawsuit or other proceeding has then been filed against the Company or its affiliates with respect to such investigation, and shall not do so unless legally required. Upon presentation of appropriate documentation, the Company shall pay or reimburse you for all reasonable out-of-pocket travel, duplicating or telephonic expenses incurred by you in complying with this Section.

12. Release. In exchange for the payments and other consideration under this Agreement, to which you would not otherwise be entitled, and except as otherwise set forth in this Agreement, you, on behalf of yourself and, to the extent permitted by law, on behalf of your spouse, heirs, executors, administrators, assigns, insurers, attorneys and other persons or entities, acting or purporting to act on your behalf (collectively, the "Employee Parties"), hereby generally and completely release, acquit and forever discharge the Company, its parents and subsidiaries, and its and their officers, directors, managers, partners, agents, representatives, employees, attorneys, shareholders, predecessors, successors, assigns, insurers and affiliates (the "Company Parties") of and from any and all claims, liabilities, demands, contentions, actions, causes of action, suits, costs, expenses, attorneys' fees, damages, indemnities, debts, judgments, levies, executions and obligations of every kind and nature, in law, equity, or otherwise, both known and unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to agreements, events, acts or conduct at any time prior to and including the execution date of this Agreement, including but not limited to: all such claims and demands directly or indirectly arising out of or in any way connected with your employment with the Company or the termination of that employment; claims or demands related to salary, bonuses, commissions, stock, stock options, or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, severance pay, or any other form of compensation; claims pursuant to any federal, state or local law, statute, or cause of action; tort law; or contract law (individually a "Claim" and collectively "Claims"). The Claims you are releasing and waiving in this Agreement include, but are not limited to, any and all Claims that any of the Company Parties:

- has violated its personnel policies, handbooks, contracts of employment, or covenants of good faith and fair dealing;

- has discriminated against you on the basis of age, race, color, sex (including sexual harassment), national origin, ancestry, disability, religion, sexual orientation, marital status, parental status, source of income, entitlement to benefits, any union activities or other protected category in violation of any local, state or federal law, constitution, ordinance, or regulation, including but not limited to: the Age Discrimination in Employment Act, as amended ("ADEA"); Title VII of the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991; 42 U.S.C. § 1981, as amended; the Equal Pay Act; the Americans With Disabilities Act; the Genetic Information Nondiscrimination Act; the Family and Medical Leave Act; Delaware Discrimination in Employment Act; the Delaware Equal Accommodations Law; the Delaware Persons With Disabilities Employment Protections Act; the Fair Employment Practice Act of Maryland, Md. Code Ann., State Government, tit. 20; the Employee Retirement Income Security Act; the Employee Polygraph Protection Act; the Worker Adjustment and Retraining Notification Act; the Older Workers Benefit Protection Act; the anti-retaliation provisions of the Sarbanes-Oxley Act, or any other federal or state law regarding whistleblower retaliation; the Lilly Ledbetter Fair Pay Act; the Uniformed Services Employment and Reemployment Rights Act; the Fair Credit Reporting Act; and the National Labor Relations Act;

- has violated any statute, public policy or common law (including but not limited to Claims for retaliatory discharge; negligent hiring, retention or supervision; defamation; intentional or negligent infliction of emotional distress and/or mental anguish; intentional interference with contract; negligence; detrimental reliance; loss of consortium to you or any member of your family and/or promissory estoppel).

Notwithstanding the foregoing, other than events expressly contemplated by this Agreement you do not waive or release rights or Claims that may arise from events that occur after the date this waiver is executed and you are not releasing any right of indemnification you may have for any liabilities arising from your actions within the course and scope of your employment with the Company or within the course and scope of your role as a member of the Board of Directors or officer of the Company. Also excluded from this Agreement are any Claims which cannot be waived by law, including, without limitation, any rights you may have under applicable workers' compensation laws and your right, if applicable, to file or participate in an investigative proceeding of any federal, state or local governmental agency. Nothing in this Agreement shall prevent you from filing, cooperating with, or participating in any proceeding or investigation before the Equal Employment Opportunity Commission, United States Department of Labor, any other federal government agency, or similar state or local agency, or exercising any rights pursuant to Section 7 of the National Labor Relations Act. However, you are waiving, to the fullest extent permitted by law, your right to any monetary recovery should any governmental agency or entity, such as the Equal Employment Opportunity Commission, the United States Department of Labor or the National Labor Relations Board, pursue any Claims on your behalf. If any Claim is not subject to

release, to the extent permitted by law, you waive any right or ability to be a class or collective action representative or to otherwise participate in any putative or certified class, collective or multi-party action or proceeding based on such a Claim in which any of the Company Parties is a party. This Agreement does not abrogate your existing rights under any Company benefit plan or any plan or agreement related to equity ownership in the Company; however, it does waive, release and forever discharge Claims against the Company existing as of the date you execute this Agreement pursuant to any such plan or agreement.

13. Your Acknowledgments and Affirmations/ Effective Date of Agreement. You acknowledge that you are knowingly and voluntarily waiving and releasing any and all rights you may have under the ADEA, as amended. You also acknowledge and agree that (i) the consideration given to you in exchange for the waiver and release in this Agreement is in addition to anything of value to which you were already entitled, and (ii) that you have been paid for all time worked, have received all the leave, leaves of absence and leave benefits and protections for which you are eligible, and have not suffered any on-the-job injury for which you have not already filed a Claim. You affirm that all of the decisions of the Company Parties regarding your pay and benefits through the date of your execution of this Agreement were not discriminatory based on age, disability, race, color, sex, religion, national origin or any other classification protected by law. You affirm that you have not filed or caused to be filed, and are not presently a party to, a Claim against any of the Company Parties. You further affirm that you have no known workplace injuries or occupational diseases. You acknowledge and affirm that you have not been retaliated against for reporting any allegation of corporate fraud or other wrongdoing by any of the Company Parties, or for exercising any rights protected by law, including any rights protected by the Fair Labor Standards Act, the Family Medical Leave Act or any related statute or local leave or disability accommodation laws, or any applicable state workers' compensation law. You further acknowledge and affirm that you have been advised by this writing that: (a) your waiver and release do not apply to any rights or Claims that may arise after the execution date of this Agreement; (b) you have been advised hereby that you have the right to consult with an attorney prior to executing this Agreement; (c) you have been given twenty-one (21) days to consider this Agreement (although you may choose to voluntarily execute this Agreement earlier and if you do you will sign the Consideration Period waiver below); (d) you have seven (7) days following your execution of this Agreement to revoke this Agreement; and (e) this Agreement shall not be effective until the date upon which the revocation period has expired unexercised (the "Effective Date"), which shall be the eighth day after this Agreement is executed by you.

14. No Admission. This Agreement does not constitute an admission by the Company of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights. The Company agrees not to disparage you in any manner likely to be harmful to you or your business, business reputation or personal reputation; provided that the Company will respond accurately and fully to any question, inquiry or request for information when required by legal process. The Company's obligations under this Section are limited to Company representatives with knowledge of this provision.

15. Breach. The parties agree that a material breach of this Agreement by one party excuses performance by the other party. Further, you acknowledge that it may be impossible to assess the damages caused by your violation of the terms of Sections 8, 9, and 10 of this Agreement and further agree that any threatened or actual violation or breach of those Sections of this Agreement will constitute immediate and irreparable injury to the Company. You therefore agree that any such breach of this Agreement is a material breach of this Agreement, and, in addition to any and all other damages and remedies available to the Company upon your breach of this Agreement, the Company shall be entitled to an injunction to prevent you from violating or breaching this Agreement. If either party is successful in whole or part in any legal or equitable action to enforce this Agreement, then the enforcing party can recover from the other party all of the costs, including reasonable attorneys' fees, incurred in enforcing the terms of this Agreement.

16. Section 409A. The Company is offering severance to you in reliance on Treasury Regulation Section 1.409A-1(b)(9) and the short term deferral exemption in Treasury Regulation Section 1.409A-1(b)(4). Any payments made in reliance on Treasury Regulation Section 1.409A-1(b)(4) will be made not later than March 15, 2016. For purposes of Code Section 409A, your right to receive any installment payments under this letter (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

17. Miscellaneous. This Agreement, including Exhibits A and B, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of Delaware as applied to contracts made and to be performed entirely within Delaware.

If this Agreement is acceptable to you, please sign below and return the original to me on or before the date that is twenty-one (21) days after you have received this letter, but no earlier than December 31, 2015. The Company's offer contained herein will automatically expire if we do not receive the fully signed Agreement by that date.

I wish you good luck in your future endeavors.

Sincerely,

CERECOR INC.

By: /s/ Mariam E. Morris
Mariam E. Morris
Chief Financial Officer

AGREED TO AND ACCEPTED:

/s/ Blake M. Paterson
Blake M. Paterson

January 1, 2016

Exhibit 10.17

CERECOR INC.

Non- Employee Director Compensation Policy

Amended January 10, 2016

Each member of the Board of Directors (the " ***Board***") who is not also serving as an employee of **Cerecor Inc.** (the "***Company***") or any of its subsidiaries (each such member, an " ***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service on and following the date this policy is adopted by the Compensation Committee of the Board (the "***Effective Date***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This policy is effective as of the Effective Date and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each calendar quarter in which service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a calendar quarter, each retainer set forth below for such quarter will be pro-rated based on days served in the applicable calendar quarter, with regular full quarterly payments thereafter. Likewise, if an Eligible Director ceases to serve on the Board or a committee of the Board at a time other than effective as of the last day of a calendar quarter, each retainer set forth below for such quarter will be pro-rated based on days served in the applicable calendar quarter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:

    a. All Eligible Directors: $35,000
    b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $25,000

2. Annual Committee Member Service Retainer:

    a. Member of the Audit Committee: $7,500
    b. Member of the Compensation Committee: $5,000
    c. Member of the Nominating and Corporate Governance Committee: $3,500

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3 . Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):

a. Chairman of the Audit Committee: $7,500
b. Chairman of the Compensation Committee: $5,000
c. Chairman of the Nominating and Corporate Governance Committee: $3,500

Election to Receive Stock Options in Lieu of Cash

An Eligible Director may make an election to receive all or a portion of his or her annual cash compensation described above in the form of stock options to purchase shares of the Company's common stock (the "***Common Stock***"). Elections must be made in multiples of 5% of an Eligible Director's aggregate cash retainer.

1. Timing of Elections:

a. *Current Eligible Directors*: Elections must be made prior to the beginning of each quarter.
b. *New Eligible Directors*: Elections for the first quarter of service must be made within 30 days of becoming an Eligible Director, provided that such election shall be applicable only to the portion of the cash retainers earned after the date of the election.
c. *New committee member or committee chair*: Elections for the first quarter of service must be made prior to the date that the Eligible Director becomes a committee member or committee chair (or, if a new Eligible Director, within 30 days of becoming a committee member or committee chair, provided that such election shall be applicable only to the portion of the cash retainer earned after the date of the election).

2 . Description of Stock Options: The stock options will be granted under the Company's 2015 Omnibus Incentive Compensation Plan (the "***Plan***"). The stock options will be granted on the date on which the cash would otherwise have been paid (i.e. on the last day of each calendar quarter). All stock options granted will be nonqualified stock options using the Company's standard form of Nonqualified Stock Option Grant Agreement under the Plan, with an exercise price per share equal to the last reported sale price of the Common Stock on the NASDAQ Capital Market on the date of grant or, if such grant date is not a trading date, on the last trading date prior to the grant date, and with a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan). The actual number of shares subject to the stock options will be determined so that the options have a "fair value" on the date of grant, using a Black-Scholes or binominal valuation model consistent with the methodology used by the Company in preparing its financial statements, equal to the amount of cash fees forgone. The stock options will immediately vest and become exercisable in full upon grant.

Equity Compensation

The equity compensation set forth below will be granted under the Plan. All stock options granted under this policy will be nonqualified stock options using the Company's standard form of Nonqualified Stock Option Grant Agreement under the Plan, with an exercise price per share equal to the last reported sale price of the Common Stock on the NASDAQ Capital Market on the date of grant or, if such grant date is not a trading date, on the last trading date prior to the grant date, and with a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1 . Initial Grant for New Eligible Directors: For each Eligible Director who is first appointed or elected to the Board following the Effective Date, on the date of such election or appointment (or, if such date is not a market trading day, the first market trading day thereafter), such Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, be granted a stock option for 16,714 shares of Common Stock. The stock options will vest and become exercisable in three substantially equal annual installments on the first, second and third anniversary of the date of grant, subject to the Eligible Director's continued service on each such vesting date.

2 . Annual Grant: On the date of each annual stockholders meeting of the Company held after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholders meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, be granted a stock option for 8,357 shares of Common Stock. The stock options will vest and become exercisable in full on the first anniversary of the grant date, subject to the Eligible Director's continued service on such vesting date.

Exhibit 21.1

List of Subsidiaries

None.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-207949) pertaining to the 2015 Omnibus Incentive Compensation Plan of Cerecor Inc. of our report dated March 23, 2016, with respect to the financial statements of Cerecor Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2015.

/s/ Ernst & Young LLP

Baltimore, Maryland
March 23, 2016

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Uli Hacksell, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cerecor Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2016

/s/ Uli Hacksell
Uli Hacksell
President and Chief Executive Officer
(Registrant's Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mariam E. Morris, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cerecor Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2016

/s/ Mariam E. Morris
Mariam E. Morris
Chief Financial Officer
(Registrant's Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Cerecor Inc. (the "Registrant") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Uli Hacksell, Chief Executive Officer of the Registrant, and I, Mariam E. Morris, Chief Financial Officer of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 23, 2016

By: /s/ Uli Hacksell
Name: **Uli Hacksell**
Title: **Chief Executive Officer (Registrant's Principal Executive Officer)**

Date: March 23, 2016

By: /s/ Mariam E. Morris
Name: **Mariam E. Morris**
Title: **Chief Financial Officer (Registrant's Principal Financial and Accounting Officer)**

The foregoing certifications are not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and are not to be incorporated by reference into any filing of Cerecor Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.