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

Prospectus Supplement No. 30
(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

This prospectus supplement No. 30 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, the prospectus supplement No. 11 dated April 11, 2016, the prospectus supplement No. 12 dated May 25, 2016, the prospectus supplement No. 13 dated May 26, 2016, the prospectus supplement No. 14 dated May 26, 2016, the prospectus supplement No. 15 dated July 20, 2016, the prospectus supplement No. 16 dated August 15, 2016, the prospectus supplement No. 17 dated August 29, 2016, the prospectus supplement No. 18 dated September 6, 2016, the prospectus supplement No. 19 dated September 12, 2016, the prospectus supplement No. 20 dated September 21, 2016, the prospectus supplement No. 21 dated September 26, 2016, the prospectus supplement No. 22 dated November 8, 2016, the prospectus supplement No. 23 dated November 29, 2016, the prospectus supplement No. 24 dated December 5, 2016, the prospectus supplement No. 25 dated January 20, 2017, the prospectus supplement No. 26 dated January 27, 2017, the prospectus supplement No. 27 dated January 30, 2017, the prospectus supplement No. 28 dated March 2, 2017 and the prospectus supplement No. 29 dated March 13, 2017, 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 14, 2017.

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 March 14, 2017

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, 2016
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 10, 2017, there were 10,744,959 outstanding shares of the registrant's common stock, par value $0.001 per share. The aggregate market value of shares of common stock held by non-affiliates as of December 31, 2016 was $6.8 million.

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, 2016, 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, the timing and results of clinical trials, the potential attributes and benefits of our product candidates, the use and sufficiency of capital resources 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 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. Other than three third-party sponsored trials of one of our product candidates, CERC-501, we do not have any ongoing clinical trials of our product candidates. We will require additional funding to further advance the development of our product candidates. We are currently preparing an investigational new drug application, or IND, for CERC-611, but we would require additional funding to advance it into clinical trials. Our portfolio of product candidates is summarized below:

- ***CERC-501: Adjunctive Treatment of Major Depressive Disorder.*** CERC-501 is a potent and selective kappa opioid receptor, or KOR, antagonist, or inhibitor, taken by mouth. It is being developed as an adjunctive treatment of major depressive disorder, or MDD. KORs have been shown to play an important role in stress, mood and addiction. CERC-501 is active in animal models of depression and addiction, and it has been generally well tolerated in four human clinical trials. Currently, three externally funded clinical trials are being conducted to evaluate the use of CERC-501 in treating depressive symptoms, stress-related smoking relapse and cocaine addiction. One trial is being conducted under the auspices of the National Institute of Mental Health, the second trial is a collaboration between Cerecor and Yale University with funding from the National Institutes of Health and the third trial is being conducted at Rockefeller University Hospital with funding from a private foundation. We recently completed a Phase 2 clinical trial for CERC-501 for smoking cessation that was partially funded by a grant from the National Institute on Drug Abuse at NIH. This trial evaluated the effect of 15 mg of CERC-501 administered orally once per day on tobacco reinstatement behavior and assessed subjects' craving, mood and anxiety during abstinence periods. In December 2016, we reported that CERC-501 did not meet its primary efficacy endpoint in this trial, but it was generally well tolerated. We plan to initiate a Phase 2/3 clinical trial with CERC-501 as an adjunctive treatment of MDD in the next year, subject to the availability of additional funding.

- ***CERC-301: Adjunctive Treatment of Major Depressive Disorder.*** We are developing CERC-301 as an oral, adjunctive treatment for patients with 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 U.S. Food and Drug Administration, or FDA, in 2013 for CERC-301 for the treatment of MDD. CERC-301 belongs to a class of compounds known as antagonists 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, such as ketamine. We recently completed a Phase 2 clinical trial for CERC-301 for the treatment of MDD, in which we evaluated the effect of intermittent oral doses of 12 mg and 20 mg versus placebo. In November 2016, we reported that CERC-301 did not meet its primary endpoint in this trial, but we observed a numerical separation from placebo of the 20 mg dose on day 2, which we believe may correspond to a clinically meaningful treatment effect. We are currently evaluating potential next steps for this program.

- ***CERC-611: Adjunctive Treatment of Partial-Onset Seizures in Epilepsy.*** CERC-611 is a potent and selective transmembrane AMPA receptor regulatory proteins, or TARP, γ-8-dependent α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid, or AMPA, receptor antagonist, or inhibitor. TARPs are a recently discovered family of proteins that have been found to associate with, and modulate the activity of, AMPA receptors. TARP γ-8-dependent AMPA receptors are localized primarily in the hippocampus, a region of the brain with importance in complex partial seizures and particularly relevant to seizure origination and/or propagation. We believe CERC-611 is the first drug candidate to selectively target and functionally block region-specific AMPA receptors after oral dosing, which we believe may improve the efficacy and side effect profile of CERC-611 over current anti-epileptics. Research also suggests that selectively targeting individual TARPs may enable selective modulation of specific brain circuits without globally affecting synaptic transmission. We plan to file an IND, with the FDA in 2017. Subject to the availability of additional funding, and, if clearance is received from the FDA, we plan to commence Phase 1 development in 2017. We intend to develop CERC-611 as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy.

- ***CERC-406: Cognitive Impairment.*** CERC-406 is our preclinical candidate that inhibits catechol-O-methyltransferase, or COMT, within the brain. We believe CERC-406 has potential as a treatment of residual cognitive impairment symptoms in patients with MDD among other psychiatric and neurological conditions frequently impacted by impaired cognition.

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 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.

Our key strategic objectives include:

- ***Pursue financing arrangements to fund pipeline development.*** We are evaluating opportunities to fund the future development of our clinical product candidates through financing arrangements that provide us with the capital required to achieve our development objectives.

- ***Pursue non-dilutive funding of pipeline development.*** We are exploring opportunities to fund our development programs through collaborations and grants from the government and private foundations, as well as out-licensing arrangements.

- ***Explore strategic alternatives focused on maximizing stockholder value.*** We are reviewing a range of strategic alternatives focused on maximizing stockholder value. Potential strategic alternatives that may be explored or evaluated include an acquisition, merger, business combination or other strategic transaction.

- ***Develop CERC-501 as an adjunctive treatment of MDD.*** Subject to the availability of additional funding, in the next year we will prepare CERC-501 for a Phase 2/3 clinical trial as an adjunctive treatment of MDD in patients with an inadequate response to standard antidepressant therapies. We believe that preclinical and recent clinical evidence supports the use of other KOR antagonists as novel medicines for the treatment of mood- and stress-related conditions, such as MDD. We believe CERC-501 has similar potential.

- ***Develop CERC-611 as an adjunctive therapy for seizures in patients with epilepsy.*** We believe CERC-611 is the first molecule to selectively target and functionally block regionally-specific AMPA receptors after oral dosing and the efficacy and side effect profile may represent an improvement compared to current antiepileptics. We intend to submit an IND with the FDA and, upon acceptance, commence Phase 1 development of CERC-611 in 2017, subject to the availability of additional funding.

Disease Overview

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.

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. 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. Accumulating clinical evidence suggests that cognitive dysfunction is a core psychopathological feature of the disorder.

Epilepsy

Disease Overview and Treatment Limitations

It is estimated the epilepsy patient population in the US, Japan, and five major EU markets (France, Germany, Italy, Spain, and the UK) will increase from 4.6 million cases in 2012 to 5.1 million cases by 2020, representing an increase of 10.7%. The US will have the largest number of diagnosed epilepsy cases across the aforementioned markets, with approximately 2.35 million patients by 2020. It has been reported that there are approximately 150,000 new cases of epilepsy diagnosed annually in the US alone. Epilepsy constitutes an area in which there is still significant unmet medical need, with up to 40% of patients not achieving seizure freedom despite therapy with currently available antiepileptic drugs, or AEDs.

Epilepsy is broadly classified according to whether the contributing seizures are partial-onset or generalized. While the two subtypes produce seizures with different characteristics, the differentiation is most important when deciding upon the appropriate course of treatment. Certain therapies are more effective in partial-onset or generalized seizures, and drugs only gain approval for the seizure subtype in which there is proven efficacy.

According to research conducted by Datamonitor Healthcare of 217 neurologists in the US, Japan, and the five major EU markets , two-thirds of epilepsy patients experience partial-onset seizures, while generalized seizures account for around one-third of cases. There was broad agreement across the countries investigated, with neurologists from every market stating that partial-onset seizures are the predominant seizure type. These figures are consistent with the published literature, with multiple studies also assigning the proportion of epilepsy cases being due to partial-onset seizures in the range of 60% to 67%

Although a large number of treatment options, both pharmacologic and non-pharmacologic, are available to epilepsy patients, a sizable proportion fail to respond to therapy and have so-called treatment-resistant epilepsy. According to the International League Against Epilepsy, or ILAE, treatment-resistant epilepsy, also known as drug-resistant epilepsy, is defined as the failure of adequate trials of two tolerated, appropriately chosen and used anti-epileptic drug schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom. These patients continue to experience seizures, which not only affects quality of life, but may lead to serious consequences, including shortened lifespan, bodily injury, neuropsychologic and psychiatric impairment, and social disability. Mortality rates are estimated to be four to seven times higher in people with treatment-resistant seizures compared to the general population. The results from Datamonitor Healthcare's research are broadly in line with the latest estimates in the published literature. As the definition of treatment-resistant epilepsy is not yet standardized - the ILAE definition is only a proposal - reported prevalence varies between 20% and 40% of all epilepsy cases.

One type of epilepsy of particular interest is temporal lobe epilepsy, or TLE. TLE is the most common form of partial-onset or localization related epilepsy. It accounts for approximately 60% of all patients with epilepsy. There are two types of TLE; one involves the medial or internal structures of the temporal lobe, or MTLE, while the second, called neocortical temporal lobe epilepsy, involves the outer portion of the temporal lobes. The most common is MTLE, which accounts for 80% of all TLEs. MTLE often begins within a structure of the brain called the hippocampus. It is frequently resistant to currently available medications and is associated with hippocampal sclerosis. Surgery is often the only treatment available.

Current AED therapies target a variety of mechanisms, including gamma-aminobutyric acid, or GABA, receptor agonism, T-type calcium channel blockers, sodium channel modulators, synaptic vesicle glycoprotein 2A, or SV2A, modulation, and inhibition of GABA transaminase. More recently, AMPA receptor antagonists have been investigated and approved for treatment of epilepsy as well.

The chosen AEDs are very similar for partial-onset seizures, irrespective of whether patients respond to treatment or remain refractory. According to Datamonitor Healthcare's research, levetiracetam remains the most commonly prescribed drug (50.6% of patients), with lamotrigine (32.4%) and carbamazepine (27.3%) second and third, respectively. However, it is notable that each drug's patient share is increased, reflecting the increased willingness of neurologists to prescribe each drug as part of a combination therapy. The National Institute for Health and Care Excellence guidelines state that various drugs - including carbamazepine, clobazam, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, sodium valproate, or topiramate - should all be considered as adjunctive treatment if initial monotherapy was ineffective or not tolerated.

The sum of all drugs patient shares in the Datamonitor Healthcare survey is over 200%, suggesting that the typical patient receives two AEDs on average to control their treatment-refractory partial-onset seizures. This trend is apparent in each of the US, Japan, and the five major EU markets.

Unmet Needs

Continuous medication with AEDs is necessary even after the seizures have long been suppressed with treatments. AEDs can prevent seizures from happening but are not effective in stopping seizures once they are underway and do not cure epilepsy; that is, they are anti-seizure, but not anti-epileptogenic. Therefore, currently available AEDs should be classified as symptomatic drugs against ictogenesis.

No marketed or pipeline drugs have yet demonstrated anti-epileptogenic properties in humans. In the past 20 years, many new AEDs have come on to the market with the promise of improved seizure control and minimal side effects. Nevertheless, there remain several key unmet needs in the treatment of epilepsy that pharmaceutical companies can target.

1. Effective treatments for refractory epilepsy subtypes: Despite advances in treatment, the efficacy of current AEDs remains limited, with up to 40% of patients continuing to suffer from uncontrolled seizures (known as refractory epilepsy) despite trying several medications. When two AEDs have failed as monotherapy, the chance of seizure freedom with further monotherapy is very low. Uncontrolled seizures have approximately 40 times higher risk of inflicting mortality.

   These patients not only continue to have quality of life-limiting seizures, but may also have other serious consequences, including shortened lifespan, bodily injury, neuropsychologic and psychiatric impairment, and social disability. Mortality rates are estimated to be four to seven times higher in people with treatment-resistant seizures compared to the general population. Consequently, the development of new AEDs with efficacy in treatment-refractory seizures remains an unmet need for improving the quality of life for a substantial proportion of epilepsy sufferers.

2. AEDs with safer and more tolerable side-effect profiles: Adverse effects from AEDs are common and a major cause of discontinuing drug treatment. The side effects of epilepsy drugs vary widely, and include fatigue, nausea, vomiting, and long-term problems such as osteoporosis. Additionally, some AEDs may produce weight gain (such as valproate), while others may induce weight loss (such as zonisamide and topiramate). Therefore, a significant unmet need in epilepsy treatment is the availability of AEDs that are effective in controlling seizure activity in doses that do not induce adverse side effects.

   In producing a dampening effect on neuronal activity in the brain, AEDs have the potential to alter the neurochemical mechanisms that are responsible for thinking skills and mood. Therefore, AEDs often lead to cognitive and behavioral side effects. These side effects include impaired attention, depression, anxiety, and irritability.

   Adverse effects on cognition and behavior are an important concern with AED therapy because of the negative effect they can have on activities of daily living, such as driving and occupational functioning. For pediatric patients, reducing cognitive and behavioral side effects is of particular importance due to the potential impact they can have on learning and development. Because these side effects occur while the child's brain is still developing, long-term effects of the medication remain a possibility. Research has found that adults with childhood-onset epilepsy have fewer educational qualifications and poorer job prospects. Furthermore, the fact that these long term effects were present in adults no longer taking AEDs is indicative that drug treatment or the seizures themselves can permanently impair development. Differential cognitive and behavioral side effects have been established for some AEDs. For example, the sedating AEDs (such as valproate and carbamazepine) can cause fatigue, impaired attention, and depression, while the activating AEDs (such as felbamate and lamotrigine) can cause anxiety, insomnia, and agitation. The most commonly reported adverse effects are also similar to marketed agents and include dizziness, somnolence, irritability, headache, falls, and ataxia.

3. Better treatment options for elderly patients: According to Datamonitor Healthcare's research, there are over 1.3 million prevalent epilepsy patients aged 60 or older in the US, Japan, and the five major EU markets, representing 29% of the total prevalent epilepsy population. The management of epilepsy in the elderly population is becoming a global challenge because elderly patients frequently present with concomitant disease and age-related alterations in renal and hepatic function that alter drug metabolism. The changes in metabolism and excretion of drugs associated with aging can result in increased susceptibility to neurotoxic side effects. Furthermore, as many elderly patients are on existing drug treatment for other disorders, the risk of drug interactions is exacerbated.

Product Pipeline

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

Product Candidate / Platform	Potential Indication(s)	Stage of Development	Anticipated Milestones
CERC-501	Adjunctive treatment of MDD	Phase 2	Initiate Phase 2/3 studies in the next year, subject to the availability of additional funding
CERC-301	Adjunctive treatment of MDD with rapid onset	Phase 2	Next steps being evaluated
CERC-611	Adjunctive treatment of partial-onset seizures in epilepsy	Preclinical	IND submission and initiate Phase 1 studies in 2017, subject to the availability of additional funding
CERC-406	Residual cognitive impairment symptoms in MDD	Preclinical	IND submission (timing dependent on the availability of additional funding)

CERC-501

Adjunctive Treatment of Major Depressive Disorder

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 adjunctive treatment of MDD.

We believe CERC-501 may have the following advantages over conventional antidepressant therapies:

- highly specific and selective to KOR and, therefore, minimal off-target pharmacology;
- available in convenient, once-a-day oral dosing; and
- potential efficacy against addictive 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

conducted by other parties, 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. We believe these studies provide the basis for further evaluation of the use of KOR antagonists, like CERC-501, in mood and substance use disorders.

Our Program

Current Development Status

Subject to the availability of additional funding, we intend to develop CERC-501 as an adjunctive treatment of MDD. We believe CERC-501 has potential as an adjunctive treatment of MDD taken once-a-day by mouth.

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 three external clinical trials that are currently being conducted to evaluate the use of CERC-501 in treating depressive symptoms, stress-related smoking relapse and cocaine addiction. The following is a summary of these three clinical trials:

- *Impact of the KOPr Antagonist OpRA Kappa in Persons at Specific Stages of Cocaine Addiction Trajectory, Versus Normal Volunteers*. This single site 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 and is being conducted under the auspices of the National Institute of Mental Health.

- *Does CERC-501 Attenuate Stress-Related Smoking Lapse?* This trial, which enrolled its first subject in August 2016, is a collaborative effort between Cerecor and Dr. Sherry McKee of Yale University and is supported by funding from the National Institutes of Health.

CERC-301

Adjunctive Treatment of Major Depressive Disorder

CERC-301 is an oral and specific NR2B antagonist that we are 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 acquired MK-0657, which is now known as CERC-301, from Merck & Co., Inc., or 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.

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.

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.

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 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;
- 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. In November 2016, we announced the top-line clinical results from our Phase 2 clinical trial (Clin301-203) with CERC-301 for the adjunctive treatment of MDD. CERC-301 missed the primary endpoint but the 20 mg dose showed signals of efficacy at day 2. We are currently assessing the next steps for development of this product candidate.

CERC-611

Adjunctive Treatment of Partial-Onset Seizures in Epilepsy

We acquired LY3130481, which is now known as CERC-611, from Lilly in June, 2016 through an exclusive worldwide license. We believe CERC-611is the first molecule to selectively target and functionally block region-specific AMPA receptors after oral dosing. This selectivity was engineered into CERC-611 by chemical SAR studies to achieve selective blockade of the AMPA receptor regulator protein or TARP γ-8 (high density in hippocampus, a region of importance in partial-onset epilepsies) while sparing AMPA receptors associated with TARP γ-2 (high density in cerebellum regulating the ataxia and falling associated with perampanel-Fycompa™). Because of the predominant hippocampal location of TARP γ-8-dependent AMPA receptors, we believe that the efficacy and side effect profile of CERC-611 may be improved compared to current antiepileptics.

We believe CERC-611may:

- Have efficacy in refractory partial-onset seizures as an adjunctive therapy. It may be uniquely qualified to treat temporal lobe seizures, unlike any other current or pipeline therapy, due to its selectivity for the TARP γ-8-dependent AMPA receptors
- Lack sedative, ataxic, or falling side effects of global AMPA receptor antagonists such as perampanel-Fycompa™
- Have a reduced or absent requirement for multi-week dose titration
- Potentially mitigate some of the side-effect liabilities associated with other conjointly administered antiepileptic medications.

Emergence of AMPA Receptor Antagonists as Anti-Epileptic Drugs (AEDs)

AMPA receptors are glutamate-sensitive ion channels on postsynaptic membranes of excitatory synapses in the central nervous system and are largely responsible for mediating fast neurotransmission across synaptic gaps. AMPA receptor antagonists are known anticonvulsant agents and their ability to down modulate excitatory neurotransmission is key to their anti-epileptic therapeutic potential. However, because AMPA receptor activity is so ubiquitous in the central nervous system, or CNS, general antagonism affects most areas of the CNS, resulting in undesired effects, such as ataxia, falls, sedation, and/or dizziness, which are shared by all known general or broad spectrum AMPA receptor antagonists, e.g., parampanel, talampanel. Typically these general or broad spectrum antagonists have a very narrow therapeutic dosing window, meaning that typically the doses needed to obtain anticonvulsant activity are close to or overlap with doses at which undesired effects are observed.

TARPs are a fairly recently discovered family of proteins that have been found to associate with and modulate the activity of AMPA receptors. Several TARPs are fairly region-specific in the brain, leading to physiological differentiation of the AMPA receptor activity. As for example, TARP γ-2 (stargazing)-dependent AMPA receptors are primarily localized in the cerebellum and cerebral cortex and TARP γ-8-dependent AMPA receptors are localized primarily in the hippocampus, a region particularly relevant to seizures origination and/or propagation. It has been theorized that targeting individual TARPs may enable selective modulation of specific brain circuits without globally affecting synaptic transmission.

Our Program

Current Development Status

Our plan is to develop, register and commercialize CERC-611 as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy aged 12 years and older. Our first step is to simultaneously complete technology transfer with Lilly and also complete and submit the IND to the FDA. Once the IND has been reviewed and accepted we plan to initiate Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical studies, subject to the availability of additional funding. If we are successful in demonstrating continued safety and tolerability in these studies we anticipate progressing development into Phase 2 efficacy and dose ranging studies in epilepsy.

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, subject to the availability of funding. These programs will target the improvement of working memory and executive function, which are key components of cognition.

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.

CERC-406

CERC-406 is a small, orally active molecule and is a selective COMT inhibitor with low inhibitory activity on peripheral COMT. We intend 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, subject to the availability of additional funding.

Other Business Development Activities

From time to time we may consider strategic transactions, such as mergers and 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-501, CERC-301, CERC-611 and CERC-406. 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-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-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-611.*** We possess worldwide exclusive rights to manufacture, use and sell LY3130481, now known as CERC-611. The CERC-611 patent portfolio consists of two patent families. The first family includes a U.S. patent and close to 50 international applications with composition of matter and use claims for CERC-611. The projected expiration date of the U.S. patent, exclusive of any patent term extension, is November 20, 2033. The second family includes U.S. and international applications with composition of matter and use claims of varying scope for additional selective TARP γ-8-dependent AMPA receptor antagonists. If granted, patents in the second family are expected to expire on or after May 21, 2035, depending on possible patent term adjustment and/or extension.

- ***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.

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-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.

CERC-611

As part of the exclusive license agreement with Lilly, we assumed all accountability and responsibility for existing drug substance of CERC-611, as well as all future manufacturing of CERC-611 for development and commercialization. Technology transfer from Lilly to Cerecor is ongoing including identifying and qualifying manufacturers to provide the active pharmaceutical ingredient, drug product and fill-and-finish services prior to submission of the IND and start of Phase 1 clinical studies.

License Agreements

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 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 expires 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 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 expires 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-611 License

In September 2016, we entered into an exclusive license agreement with Lilly pursuant to which we received exclusive, global rights to develop and commercialize CERC-611, previously referred to as LY3130481. In connection with the license, we granted Lilly a right of first negotiation to obtain an exclusive, worldwide license and/or other worldwide rights to develop or commercialize a licensed 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 licensed 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 any licensed products and will have no further obligation to Lilly regarding such licensed products.

The terms of the license agreement provide for an upfront payment of $2.0 million, of which $750,000 was due within 30 days of the effective date of the license agreement, and the remaining balance of $1.25 million is due after the first subject is dosed with CERC-611 in a multiple ascending dose study. For the first licensed product we develop, we are required to make milestone payments in an amount not to exceed, in the aggregate, $17.5 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 $50.0 million. Upon commercialization of a licensed product, we will pay Lilly a tiered royalty on net

sales 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 covering the licensed product in such country, or (ii) 11 years from the first commercial sale of the licensed 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 expires 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-501, CERC-301, CERC-611 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, schizophrenia, epilepsy, Parkinson's disease, substance use disorders and pain and impulse control disorders, or ICDs.

CERC-501

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 successfully completed its Phase 3 development for MDD as an adjunctive antidepressant in patients with MDD. 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.

CERC-301

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-611

The epilepsy market is crowded with current therapies targeting a variety of mechanisms, including GABA receptor agonism, T-type calcium channel blockers, sodium channel modulators, synaptic vesicle protein SV2A modulation, and inhibition of GABA transaminase. More recently, a new class of AMPA receptor antagonists have been approved for the treatment of epilepsy.

CERC-611, if we are successful in developing it and it gains regulatory approval, would compete with a number of branded and generic AEDs. A few major pharmaceutical companies (GSK (Lamictal/XR), Pfizer (Lyrica)) and specialty players (UCB (Vimpat, Keppra), Lundbeck (Sabril) and Supernus (Trokendi XR)) dominate the anti-epilepsy drug therapy market. New market entrants such as Sage Pharmaceuticals and GW Pharmaceuticals are targeting difficult to treat orphan patient populations such as super-refractory status epilepticus and Dravet Syndrome, respectively. To our knowledge, there are no other TARP γ-8-dependent AMPA receptor antagonist s in development other than CERC-611.

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 not approved by the FDA.

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.

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.

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 date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Employees

As of December 31, 2016, we had 15 full-time employees, eight 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 will require additional capital to continue to fund our operations and to finance the further advancement of our product candidates, which may not be available to us on acceptable terms, or at all. Failure to obtain this necessary capital in the near term will force us to delay, limit or terminate our product development efforts or cease our operations.

At December 31, 2016, we had $5.1 million in cash and cash equivalents and $4.3 million in current liabilities. Accordingly, we do not currently have sufficient funds to finance our continuing operations beyond the short term or to further advance any of our product candidates, including our planned initiation of a Phase 2/3 clinical trial with CERC-501 as an adjunctive treatment of major depressive disorder, or MDD, in the next year, or our plan to commence Phase 1 development of CERC-611 in 2017. We will require additional capital in the near term to finance our operations and pursue any further development of our product candidates. Following the conclusion of our recent Phase 2 clinical trial for CERC-501 for smoking cessation, which failed to meet its primary efficacy endpoint, we plan to initiate a Phase 2/3 clinical trial for CERC-501 in the next year, subject to the availability of additional funding. We are assessing the results of our recent Phase 2 clinical trial for CERC-301 for MDD which failed to meet its primary efficacy endpoint but we believe suggested a potentially clinically meaningful treatment effect in the 20 mg dose, and will announce potential next steps at a later date. We plan to file an investigational new drug application, or an IND, with the FDA for CERC-611, and commence Phase 1 development in 2017 as an adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy, subject to the availability of additional funding.

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 through clinical trials, we may fail to meet our primary or secondary endpoints, which we recently reported had occurred for our Phase 2 clinical trials for CERC-301 and CERC-501, respectively, and previously had 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 and continue to evaluate the development plan for CERC-611, submit 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 the near term in sufficient amounts, we would be prevented from pursuing development and commercialization efforts and we could be required to cease operations altogether.

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. We had cash and cash equivalents of $5.1 million as of December 31, 2016.

We may be unable to issue securities under our shelf registration statement, which may have an adverse effect on our liquidity.

We have filed a shelf registration statement on Form S-3 with the SEC. The registration statement was filed in reliance on Instruction I.B.6. of Form S-3, which imposes a limitation on the maximum amount of securities that we may sell pursuant to the registration statement during any twelve-month period. At the time we sell securities pursuant to the registration statement, the amount of securities to be sold plus the amount of any securities we have sold during the prior twelve months in reliance on Instruction I.B.6. may not exceed one-third of the aggregate market value of our outstanding common stock held by non-affiliates as of a day during the 60 days immediately preceding such sale, as computed in accordance with Instruction I.B.6. This calculation will be updated immediately after we file this Annual Report on Form 10-K and we expect that the amount of securities we will be able to sell under the registration statement on Form S-3 thereafter will be approximately $3.3 million. Based on this calculation and as a result of our equity distribution agreement with Maxim, we expect that we will be unable to sell additional securities pursuant to our effective registration statement on Form S-3 for a period of twelve months following the date of the equity distribution agreement, unless and until the market value of our outstanding common stock held by non-affiliates increases significantly. If we cannot sell securities under our shelf registration, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position.

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

Our recurring operating losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. We have no current source of revenues to sustain our present activities, and we do not expect to generate revenues until, and unless, the FDA or other regulatory agencies approve our product candidates and we successfully commercialize any such product candidates. Accordingly, our ability to continue as a going concern will require us to obtain

additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

We 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, our common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital is committed to purchase up to an aggregate of $15.0 million of our shares of common stock over the 30-month term of the Purchase Agreement and our equity distribution agreement with Maxim Group LLC, or Maxim, pursuant to which we may offer and sell shares of our common stock from time to time through Maxim, acting as sales agent. 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 $16.5 million, $10.5 million and $16.1 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of $70.0 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 have incurred 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.

Raising additional capital will 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 will result in substantial 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. We have not yet demonstrated our ability to successfully develop any product candidate, 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, including most recently CERC-611, 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-501, CERC-611 and potentially CERC-301. If we fail to obtain marketing approval for and commercialize any product candidates, or experience delays in doing so, our business will be materially harmed.

Subject to the availability of additional funding, we intend to invest a significant portion of our efforts and financial resources in the development of our product candidates CERC-501, CERC-611 and possibly CERC-301. 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 our product candidates. We recently announced that neither CERC-301 nor CERC-501 reached its primary efficacy endpoint in its respective Phase 2 clinical trial. We intend to continue to pursue development of CERC-501, but we are currently evaluating the data from our CERC-301 trial and we have not finalized our plans as to its further development. We also recently in-licensed CERC-611, which has not undergone any clinical testing to date, and we are planning to prepare and file an IND with the FDA for CERC-611 and thereafter commence clinical development as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy. 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 MDD. We cannot commercialize our product candidates prior to obtaining marketing approval from the FDA. Each of our product candidates 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 any of our product candidates, we will not be able to generate product revenues in the foreseeable future, or at all.

If, following submission, our NDA for a 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 our product candidates 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 our product candidates, 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, including CERC-611 and CERC-406, 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, we recently announced neither the Phase 2 clinical trial for CERC-301 for MDD nor the Phase 2 clinical trial for CERC-501 for smoking cessation met its respective primary endpoint. Previously, the Clin301-201 study for CERC-301 failed to meet its primary endpoint and 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 have experienced delays in enrolling patients in our CERC-301 Phase 2 clinical trial, due in part we believe to the highly competitive environment for recruiting patients to clinical trials studying depression. In addition, we believe the decision by the National Institutes of Health to discontinue a Phase 2 trial for CERC-501 was 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 or to develop and commercialize our preclinical product candidates, CERC-406 and CERC-611.

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. In September 2016, we acquired exclusive worldwide rights to CERC-611, which is in preclinical development and we intend to develop as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy. We will require additional capital to finance any further preclinical development of our COMTi product candidates, such as CERC-406, and to commence clinical development of CERC-611, and such capital may not be available on attractive terms or at all. Further, our continued development of both the COMTi platform and CERC-611 will be dependent upon receiving positive preclinical and clinical data that, in our judgment, merits advancing such programs. Even if we are successful in continuing to build and expand our COMTi 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. Similarly, even if the FDA approves our IND for CERC-611, there is no guarantee that we will be successful in our efforts to advance CERC-611 into clinical trials. 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 trial, 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 planned Phase 2/3 clinical trial of 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 may use 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 trials;

- 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 CERC-501, CERC-611 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. Further, we

recently announced that neither CERC-301 nor CERC-501 met the primary endpoint in its respective Phase 2 clinical trial, and previously 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 and CERC-611, 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. Although CERC-301 was generally well tolerated in our recently completed Phase 2 clinical trial for MDD, with no serious adverse events reported and no discontinuations due to adverse events, some adverse events were reported. The most commonly reported adverse events in the trial were increases in blood pressure, dizziness, somnolence and paresthesia. Similarly, although in our previously completed Phase 2 clinical study, Clin301-201, CERC-301 was generally well tolerated, there were 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 both our most recent and prior studies were generally consistent with the prior clinical trials conducted for CERC-301, despite having administered an increased dose of CERC-301 in our most recent study. Although CERC-501 was also generally well tolerated in our recently completed Phase 2 clinical trial for smoking cessation, with no serious adverse events reported and no discontinuations due to adverse events, some adverse events were reported. The most commonly reported adverse events, over 5% and greater than placebo in the study, were diarrhea and decreased appetite.

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 if it is approved.

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 would 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. CERC-611 would compete with the non-selective AMPA receptor antagonist, Fycompa®, marketed by Esai Inc.

Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that any or our product candidates, if approved, would 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 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.

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.

Significant uncertainty exists regarding the effect of the Affordable Care Act, particularly in light of the pending change in the Administration following the recent elections and campaign pledges to repeal or reform the Affordable Care Act. However, if the new law is maintained in its current form, it appears likely that it would 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-501 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, as well as an exclusive license, development and commercialization agreement with Lilly pursuant to which we received exclusive global rights to develop and commercialize CERC-611. 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, CERC-611 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

If we are not able to comply with the applicable continued listing requirements or standards of The NASDAQ Capital Market, NASDAQ could delist our common stock.

Our common stock is currently listed on The NASDAQ Capital Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

On January 13, 2017, we received a notice from NASDAQ that we were not in compliance with NASDAQ Listing Rule 5550(b)(1), as we failed to maintain a minimum required stockholders' equity of $2.5 million, NASDAQ Listing Rule 5550(b)(2), as the market value of our listed securities, or MVLS, was below the minimum $35 million for the previous 30 consecutive business days, and NASDAQ Listing Rule 5550(b)(3), as we have not had net income from continuing operations in the latest fiscal year or in two of the last three fiscal years. In accordance with NASDAQ Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until July 12, 2017, to regain compliance with the Rule. To regain compliance, at any time during the 180 calendar day-compliance period our MVLS must close at $35 million or more for a minimum of 10 consecutive business days or we must report stockholders' equity of at least $2.5 million. If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by NASDAQ, NASDAQ will provide notice that our shares of common stock will be subject to delisting.

Additionally, on February 24, 2017, we received a notice from NASDAQ that we were not in compliance with NASDAQ Listing Rule 5550(a)(2), as we failed to maintain a minimum bid price of $1 per share for the previous 30 consecutive business days. In accordance with NASDAQ Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until August 23, 2017, to regain compliance with the Rule, which we may achieve if the closing bid price of our common stock is at least $1 for a minimum of ten consecutive business days. If we do not regain compliance within the allotted compliance period, including any extensions that may be granted by NASDAQ, NASDAQ will provide notice that our shares of common stock will be subject to delisting.

In the event that our common stock is delisted from NASDAQ and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

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.

The market price of our 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 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 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 contract research organizations 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 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 material adverse impact on the market price of our warrants or shares of common stock.

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

We expect that significant additional capital 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.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common stock would have on the market price of our common stock.

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

The continued operation and expansion of our business will require substantial funding. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

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.

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.

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 our initial public 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.

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 headcount.

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 years ended December 31, 2016 and 2015.

Year Ended December 31, 2016		
First Quarter	**High**	**Low**
Common stock	$ 4.92	$ 2.90
Class A warrants	$ 1.50	$ 0.64
Class B warrants	$ 1.08	$ 0.65
Second Quarter		
Common stock	$ 4.01	$ 1.94
Class A warrants	$ 1.20	$ 0.63
Class B warrants	$ 0.98	$ 0.40
Third Quarter		
Common stock	$ 4.91	$ 2.21
Class A warrants	$ 1.61	$ 0.45
Class B warrants	$ 0.85	$ 0.35
Fourth Quarter		
Common stock	$ 5.23	$ 0.88
Class A warrants	$ 1.99	$ 0.11
Class B warrants	$ 1.00	$ 0.02

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 2, 2017, there were approximately 67 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

On September 8, 2016, we issued and sold to Aspire Capital 250,000 shares of common stock at a price per share of $4.00, for gross proceeds of $1 million and issued to Aspire Capital 175,000 shares of common stock as a commitment fee as consideration for entering into the Purchase Agreement, both in transactions exempt from registration under the Securities Act, in reliance on Section 4(a)(2) thereof and Rule 506 of Regulation D thereunder. Aspire Capital represented that it was an "accredited investor," as defined in Regulation D, and was acquiring the Securities for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof. On September 16, 2016, we filed a Registration Statement on Form S-1 (File No. 333-213676) that registered the aggregate of 425,000 shares of our common stock sold to Aspire Capital on September 8, 2016. This Registration Statement on Form S-1 was declared effective by the SEC on September 28, 2016.

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, 2016, 2015 and 2014 and the related statements of operations for each of the three years ended December 31, 2016 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 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:	**2016**	**2015**	**2014**	**2013**
Grant revenue	$ 1,152,987	$ —	$ —	$ —
Operating expenses:				
Research and development	10,149,879	6,587,183	12,240,535	8,914,084
General and administrative	7,083,155	4,422,764	4,875,030	4,020,364
Loss from operations	(16,080,047)	(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	72,625	1,313,049	2,266,161	(121,115)
Interest income (expense), net	(464,181)	(793,205)	(1,206,187)	10,555
Total other income (expense):	(391,556)	519,844	1,059,974	(110,560)
Net loss	$ (16,471,603)	$ (10,490,103)	$ (16,055,591)	$ (13,045,008)
Net loss attributable to common stockholders	$ (16,471,603)	$ (10,490,103)	$ (3,521,153)	$ (13,126,972)
Net loss per share of common stock, basic and diluted	$ (1.87)	$ (4.71)	$ (5.48)	$ (20.72)
Weighted-average shares of common stock outstanding, basic and diluted	8,830,396	2,226,023	642,052	633,669

	As of December 31,			
Balance Sheet Data:	**2016**	**2015**	**2014**	**2013**
Cash and cash equivalents	$ 5,127,958	$ 21,161,967	$ 11,742,349	$ 3,421,480
Total assets	5,768,865	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 current liabilities	4,311,863	5,849,818	4,993,816	3,065,642
Total liabilities	5,561,863	8,573,838	10,302,027	3,065,642
Convertible preferred stock	—	—	28,345,531	19,856,633
Common stock	9,434	8,650	650	643
Additional paid-in capital	70,232,651	66,638,557	16,742,063	9,170,468
Total stockholders' equity (deficit)	207,002	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 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. At December 31, 2016, we had $5.1 million in cash and cash equivalents and $4.3 million in current liabilities. Accordingly, we do not have sufficient funds to finance our continuing operations beyond the short term. We must secure additional financing to further advance any of our product candidates, including our planned initiation of a Phase 2/3 clinical trial with CERC-501 as an adjunctive treatment of major depressive disorder, or MDD, in the next year, and our plan to commence Phase 1 development of CERC-611 in 2017. Other than three third-party sponsored trials of CERC-501, we do not have any ongoing clinical trials of our product candidates and we do not currently have the capital to undertake any such trials. We are continuing preclinical development of our preclinical product candidate, CERC-611, but we would require additional funding to advance it into clinical trials.

CERC-501 is a potent and selective kappa opioid receptor, or KOR, antagonist being developed as an adjunctive treatment of MDD. KORs are believed to play key roles in modulating stress, mood and addictive behaviors, which form the basis of co-occurring disorders. We plan to initiate a Phase 2/3 clinical study in inadequately treated subjects with MDD currently on antidepressants in the next year, subject to the availability of additional funding. Currently, three externally funded clinical trials are being conducted to evaluate the use of CERC-501 in treating depressive symptoms, stress-related smoking relapse and cocaine addiction. One trial is being conducted under the auspices of the National Institute of Mental Health, the second trial is a collaboration between Cerecor and Yale University with funding from the National Institutes of Health and the third trial is being conducted at Rockefeller University Hospital with funding from a private foundation.

CERC-301 is an oral, NR2B specific N-methyl-D-aspartate, or NMDA, receptor antagonist being developed as an adjunctive treatment of MDD. CERC-301 belongs to a class of compounds known as antagonists, or inhibitors, of the 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, such as ketamine. We are currently evaluating potential next steps for this program.

CERC-611 is a potent and selective transmembrane AMPA receptor regulatory proteins, or TARP, γ-8-dependent α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid receptor antagonist, which we plan to develop as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy. We intend to file an investigational new drug application with the FDA and thereafter commence Phase 1 development in 2017, subject to the availability of additional funding.

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 intend to develop CERC-406 for the treatment of residual cognitive impairment symptoms in patients with MDD, subject to the availability of additional funding.

Further development of our product candidates will not be possible unless we secure additional funding. Our strategy is to seek funding for our operations from further offerings of equity and debt securities, non-dilutive financing arrangements such as federal grants, collaboration agreements or out-licensing arrangements, and to explore strategic alternatives such as an acquisition, merger, or business combination. However, we may be unable to raise additional funds or enter into such other agreements or transactions on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements or

transactions in the short term, we will have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates or cease our operations altogether.

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, 2016, we had an accumulated deficit of $70.0 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. Our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern within one year of the date that our financial statements were issued, and our ability to continue as a going concern will require us to obtain additional financing to fund our operations.

We have financed our operations primarily through a public offering, private placements of our common stock and convertible preferred stock, and the issuance of debt. Our ability to become and remain profitable depends on our ability to generate product 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

The Aspire Capital Transaction

On September 8, 2016, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital committed to purchase up to an aggregate of $15.0 million of shares of our common stock over the 30-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued and sold to Aspire Capital 250,000 shares of common stock at a price per share of $4.00, for gross proceeds of $1.0 million. Additionally, as consideration for Aspire Capital entering into the Purchase Agreement, we issued 175,000 shares of common stock as a commitment fee. The net proceeds of the Aspire Capital transaction, after offering expenses, were approximately $1.9 million for the year ended December 31, 2016. As of December 31, 2016, we had sold 763,998 shares of common stock to Aspire Capital. Subsequent to December 31, 2016, we sold an additional 965,165 shares of common stock to Aspire Capital under the terms of the Purchase Agreement for gross proceeds of approximately $789,000. As of the date of this Annual Report on Form 10-K, we may not issue additional shares of common stock to Aspire Capital under the Purchase Agreement unless shareholder approval to issue additional shares is obtained.

The Maxim Group Equity Distribution Agreement

On January 27, 2017, we entered into an equity distribution agreement, or the Equity Distribution Agreement, with Maxim Group LLC, or Maxim, as sales agent, pursuant to which we may offer and sell shares of our common stock through Maxim from time to time. We have no obligation to sell any of the shares, and may at any time suspend offers under the Equity Distribution Agreement.

As of the date of this filing, we had sold 345,653 shares of our common stock through Maxim under the Equity Distribution Agreement for gross proceeds of $287,000. Immediately after we file this Annual Report on Form 10-K we expect that the amount of additional securities we will be able to sell under the registration statement on Form S-3 will be approximately $3.3 million.

Engagement of SunTrust Robinson Humphrey to Assist with Review of Strategic Alternatives

On February 7, 2017, we announced the engagement of SunTrust Robinson Humphrey, Inc., or SunTrust, as our exclusive financial advisor to assist with our ongoing process to explore and review a range of strategic alternatives focused on maximizing stockholder value. Potential strategic alternatives that may be explored or evaluated as part of this process include an acquisition, merger, business combination or other strategic transaction. We have not made a decision to pursue any specific transaction or other strategic alternative, and there can be no assurance that this ongoing process will result in any such transaction.

Components of Operating Results

Revenue

To date, we have derived all of our revenue from research grants from the National Institutes of Health. 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 candidate.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred acquiring, 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 of December 31, 2016, we had eight full-time employees who were primarily engaged in research and development. We expect our research and development expenses to decrease significantly in 2017, unless the necessary capital is raised to fund the further development of our product candidates.

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 expect our general and administrative expenses to decrease in 2017.

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 initial public offering, or IPO, in October 2015 these warrants became warrants to purchase 22,328 shares of common stock, in accordance with their 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.

As part of our IPO, the underwriter 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.

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 IPO in accordance with its terms, and the related liability was reduced to zero at that time.

Interest Expense, net

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.

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.

Grant Revenue Recognition

We recognize grant revenue when there is (i) reasonable assurance of compliance with the conditions of the grant and (ii) reasonable assurance that the grant will be received. We recognize revenue under grants in earnings on a systemic basis in the period the related expenditures for which the grants are intended to compensate are incurred.

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, 2016, we had $52.2 million of federal and Maryland state net operating loss, or NOL, carryforwards that will begin to expire in 2031. As of December 31, 2016, we had $1.8 million and $57,000 of federal and Maryland State 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, 2016, included (i) volatility of 100%, (ii) risk free interest rate of 1.65%, (iii) strike price ($8.40), (iv) fair value of common stock ($0.88), and (v) expected life of 3.8 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.

As part of our IPO 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 valuing the UPO as of December 31, 2016, include (i) volatility range of 65% to 90%, (ii) risk free interest rate range of 0.44% to 1.64%, (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 ($0.88), 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 and our stock price volatility will significantly decrease the overall valuation of the UPO, while significant increases in our stock price and 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, was 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 on the statement of operations. The Investor Rights Obligation expired upon the closing of our IPO in October 2015 in accordance with its terms, and the related liability was reduced to zero at that time.

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 the then-current fair market value of our common stock and updated assumptions in the Black-Scholes option-pricing model.

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 non-employee 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 nonemployee directors are as follows:

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.01% — 1.93%	1.64% — 1.97%	0.85% — 1.97%
Expected term of options (in years)	5.0 — 6.25	5.0 — 6.25	5.00 — 6.25
Expected stock price volatility	80% — 100.0%	70.0%	70.0%
Expected annual dividend yield	—%	—%	—%

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 from inception through November 9, 2015. 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
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
1/1/2016	360,459	$ 3.35	$ 3.35	$ 2.32
1/11/2016	21,714	$ 3.56	$ 3.56	$ 2.46 — 2.49
2/24/2016	108,591	$ 3.01	$ 3.01	$ 2.10
3/14/2016	1,000	$ 4.45	$ 4.45	$ 3.11
5/18/2016	50,142	$ 3.52	$ 3.52	$ 2.53
6/30/2016	19,044	$ 2.20	$ 2.20	$ 1.53
8/17/2016	263,000	$ 3.77	$ 3.77	$ 2.70
8/24/2016	35,000	$ 4.38	$ 4.38	$ 3.10
9/30/2016	10,303	$ 4.23	$ 4.23	$ 2.83
12/31/2016	45,989	$ 0.88	$ 0.88	$ 0.66

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

Grant Revenue

The following table summarizes our grant revenue for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Grant revenue	$ 1,153	$ —

Grant revenue was $1.2 million for the year ended December 31, 2016 and was comprised of revenue from two research and development grants awarded during the year. In April 2016, we were awarded a research and development grant of $1.02 million from the National Institute on Drug Abuse at the National Institutes of Health, or the NIDA Grant. This grant provided additional resources for the completed Phase 2 clinical trial of CERC-501. In July 2016, we were awarded a research and development grant of approximately $1.0 million from the National Institute on Alcohol Abuse and Alcoholism at the National Institutes of Health, or the NIAAA Grant. This grant provides additional resources to progress the development of CERC-501 for the treatment of alcohol use disorder. For the year ended December 31, 2016, grant revenue recognized from the NIDA Grant was $1.02 million and grant revenue recognized from the NIAAA Grant was $132,000. We did not have grant revenue in the 2015 period.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
	(in thousands)	
CERC-301	$ 2,890	$ 3,110
CERC-501	3,122	1,481
CERC-611	2,103	—
COMTi	124	260
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,534	1,367
Stock-based compensation expense	141	67
Other	236	302
	$ 10,150	$ 6,587

Research and development expenses were $10.2 million for the year ended December 31, 2016, an increase of $3.6 million compared to the 2015 period. This increase was largely due to the $2.0 million total upfront payment recorded in connection with the license of CERC-611 in September 2016, of which $750,000 was due and paid within 30 days of the effective date of the license agreement. The remaining balance of $1.25 million is due after the first subject is dosed with CERC-611 in a multiple ascending dose study and is recorded as other long term liabilities on the balance sheet at December 31, 2016. Additionally, costs for CERC-501 increased by $1.6 million, driven by the costs incurred in 2016 related to the enrollment activity and costs to complete our Phase 2 clinical trial for smoking cessation, which was completed in December. These costs were offset by $1.0 million of costs incurred in the 2015 period related to the in-licensing of CERC-501. Costs for CERC-301 decreased by $220,000 due to start-up costs incurred in 2015 to initiate our Phase 2 clinical trial for the adjunctive treatment of MDD, offset by 2016 costs related to the enrollment activity and costs to complete the trial, which was completed in November.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Salaries, benefits and related costs	$ 1,922	$ 2,326
Legal, consulting and other professional expenses	2,806	1,289
Stock-based compensation expense	1,554	328
Other	801	480
	$ 7,083	$ 4,423

General and administrative expenses were $7.1 million for the year ended December 31, 2016, an increase of $2.7 million compared to the 2015 period. Legal, consulting and other professional expenses increased by $1.5 million, attributable primarily to audit, legal and other costs resulting from becoming a public company in October 2015, as well as certain financing expenses. Stock-based compensation expense increased by $1.2 million, driven by the modification of grants made to our former chief executive officer in the first quarter of 2016 in which the exercise term was extended, as well as the grant of additional awards in 2016 to our directors, executive officers and other employees. Further, other general and administrative expenses increased by $321,000 due to business development expenses and other costs. These increases were offset by a $404,000 decrease in salaries, benefits and related costs, driven by the $528,000 of severance expense recorded in 2015 due to the resignation of our former chief executive officer, offset by salary increases effected at the close of our initial public offering in October 2015.

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, UPO liability and investor rights obligation of $73,000 during the year ended December 31, 2016 compared to a gain of $1.3 million during the 2015 period. The $73,000 gain on the change in fair value during the year ended December 31, 2016 was due to the decrease in fair value of our warrant liability and UPO liability, both attributable to the decrease in our common stock price at December 31, 2016 compared to December 31, 2015.

The $1.3 million gain on the change in fair value during the 2015 period resulted from the expiration of the investor rights obligation in October 2015 upon the closing of our initial public offering.

Interest Expense, Net

Net interest expense decreased by $329,000 for the year ended December 31, 2016 compared to the year ended December 31, 2015. The decrease was primarily due to a decrease in interest associated with a reduction in the principal balance of our secured term loan facility.

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-based compensation expense	67	202
Other	302	262
	$ 6,587	$ 12,241

Research and development expenses were $6.6 million for the year ended December 31, 2015, a decrease of $5.7 million compared to the 2014 period. This 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 $501,000 due to a reduction in preclinical trial activity. There was also a decrease of $910,000 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-based compensation expense	328	885
Other	480	595
	$ 4,423	$ 4,875

General and administrative expenses were $4.4 million for the year ended December 31, 2015, a decrease of $452,000 compared to the 2014 period. Stock-based compensation expense decreased by $557,000 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 $487,000, 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, directors' and officers' insurance expense, recruiting expense, accounting and audit fees, legal fees and consulting expenses totaling $0.6 million, primarily a result of becoming a public company in 2015. Salaries, benefits and related costs increased by $707,000, which was driven by $528,000 of severance expense recorded in 2015 due to the resignation of our former chief executive officer.

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, UPO 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 2014 period. The $1.3 million gain on the change in fair value in 2015 was 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 $413,000 for the year ended December 31, 2015 compared to the year ended December 31, 2014. The decrease was 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 was 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.

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 $16.5 million, $10.5 million and $16.1 million for the years ended December 31, 2016, 2015 and 2014, respectively. At December 31, 2016, we had an accumulated deficit of $70.0 million, net working capital of $1.4 million and cash and cash equivalents of $5.1 million. To date, we have not generated any revenues from the sale of products and we do not anticipate generating any revenues from the sale of our product candidates for the foreseeable future. Historically, we have financed our operations principally through private placements of common and convertible preferred stock, convertible and nonconvertible debt, as well as our IPO in October 2015.

We will require substantial additional financing to fund our operations beyond the short term and to continue to execute our strategy. Further development of our product candidates will not be possible unless we secure additional funding. Our strategy is to seek funding for our operations from further offerings of equity or debt securities, non-dilutive financing arrangements such as federal grants, collaboration agreements or out-licensing arrangements, and to explore strategic alternatives such as an acquisition, merger, or business combination. Based on our current 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 well into the second quarter of 2017. These factors raise substantial doubt about our ability to continue as a going concern within one year of the date that our financial statements were issued.

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 our assets, excluding intellectual property, which is 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, notwithstanding adverse results of clinical trials. 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 the interest rate increasing to 8.20%. Effective December 15, 2016, the prime rate as reported by The Wall Street Journal increased another 0.25% resulting in an increase to the interest rate, which was 8.45% as of December 31, 2016. 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, 2016 of $2.4 million.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2016, 2015 and 2014:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ (14,573)	$ (10,163)	$ (15,518)
Investing activities	(35)	(20)	(20)
Financing activities	(1,426)	19,603	23,859
Net increase (decrease) in cash and cash equivalents	$ (16,034)	$ 9,420	$ 8,321

Net cash used in operating activities

Net cash used in operating activities was $14.6 million for the year ended December 31, 2016 and consisted primarily of a net loss of $16.5 million, offset by non-cash stock-based compensation expense of $1.7 million, non-cash interest expense of $162,000 and an increase in accounts payable of $332,000.

Net cash used in operating activities was $10.2 million for the year ended December 31, 2015 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, UPO liability and Investor Rights Obligation driven by the expiration of the Investor Rights Obligation during the year and a decrease in accounts payable of $269,000. These were offset by a $1.1 million increase in accrued expenses due to increased clinical trial activities and $528,000 of accrued severance expense due to the resignation of our former chief executive officer, non-cash stock compensation expense of $395,000 and non-cash interest expense of $294,000.

Net cash used in operating activities was $15.5 million for the year ended December 31, 2014 and consisted primarily of a net loss of $16.1 million, a 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 $708,000. 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 $354,000.

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 $35,000, $20,000, and $20,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

Net cash provided by (used in) financing activities

Net cash used in financing activities was $1.4 million for the year ended December 31, 2016, which consisted of principal payments on our term loan of $3.3 million offset by net proceeds from the sale of common stock to Aspire Capital under the Purchase Agreement of $1.9 million.

Net cash provided by financing activities was $19.6 million for the year ended December 31, 2015 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.

Net cash provided by financing activities was $23.9 million for the year ended December 31, 2014 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.

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. Following the closing of our IPO in October 2015, we expect to continue 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 continue to 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 well into the second quarter of 2017, which raises substantial doubt about our ability to continue as a going concern within one year of the date that our financial statements were issued. We will require substantial additional financing to fund our operations and to continue to develop our product candidates. Our strategy is to seek funding for our operations from further offerings of equity or debt securities, non-dilutive financing arrangements such as federal grants, collaboration agreements or out-licensing arrangements, and to explore strategic alternatives such as an acquisition, merger, or business combination

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.

We will need to raise substantial additional capital in the future to fund our operations and to further develop our product candidates and we anticipate funding our operations from further offerings of equity or debt securities, non-dilutive financing arrangements such as federal grants, collaboration agreements or out-licensing arrangements, and to explore strategic alternatives such as an acquisition, merger, or business combination. However, there can be no assurance that we will be able to obtain additional equity or debt financing, or strategic alternatives, 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. There can also be no assurance that the exploration of strategic alternatives will result in any such transaction. Our future capital requirements will depend on many forward-looking factors, including:

- the progress and results of the three externally funded clinical trials being conducted for CERC-501 and changes to our development plan with respect to CERC-501, if any;

- the progress of and our ability to successfully file an IND with the FDA for CERC-611, the progress and results of any subsequent clinical trials for CERC-611 and any changes to our development plan with respect to CERC-611, 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, 2016 (in thousands):

Contractual Obligation(1)	Total	Less than one year	1 - 3 years	More than 3 years
Debt obligations(2)	$ 2,332	$ 2,332	$ —	$ —
Operating lease obligations(3)	314	155	159	—
Total contractual obligations	$ 2,646	$ 2,487	$ 159	$ —

(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 $1.4 million of future services under these agreements as of December 31, 2016. 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.

Recently Adopted Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* The amendments in this update explicitly require a company's management to assess an entity's ability to continue as a going concern within one year after the date the financial statements are issued, and to provide related footnote disclosures in certain circumstances. The new standard is effective in the first annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We adopted the new guidance in the fourth quarter of 2016. The adoption of this guidance did not impact our financial position, results of operations or cash flows, nor did it significantly impact our disclosures regarding the assessment of our ability to continue as a going concern within one year of the date that our financial statements were issued.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue From Contracts With Customers* ("ASU 2014-09"). Pursuant to this update, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, *Revenue From Contracts With Customers (Topic 606)*, which delays the effective date of ASU 2014-09 by one year. As a result, ASU 2014-09 will be effective for annual reporting periods beginning after December 15, 2017 with early adoption permitted for annual reporting periods beginning after December 15, 2016. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)* ("ASU 2016-08") and ASU No. 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing* ("ASU 2016-10"), and in May 2016 the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606), Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"), each of which clarify the guidance in ASU 2014-09 and have the same effective date as the original standard. We have not yet completed our determination of the impact of adopting ASU 2014-09, ASU 2016-08, ASU 2016-10, or ASU 2016-12 on the financial statements, although, we do not expect the impact, if any, to be significant. We expect to adopt the pronouncement on a full retrospective basis on January 1, 2018.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842).* This guidance revises existing practice related to accounting for leases under ASC 840, *Leases* ("ASC 840") for both lessees and lessors. The new guidance in ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability for nearly all leases (other than leases that meet the definition of a short-term lease). The lease liability will be equal to the present value of lease payments and the right-of-use asset will be based on the lease liability, subject to adjustment such as for initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating leases or capital leases. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while capital leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840). The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. We are currently evaluating the potential impact of the adoption of this standard on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting.* The guidance is intended to simplify several areas of accounting for share-based compensation, including income tax impacts, classification on the statement of cash flows and forfeitures. The new standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early application is permitted. We adopted this standard on January 1, 2017 and its adoption will have no impact on our financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash*. The guidance is intended to address the diversity that currently exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The new standard requires that entities show the changes in the total of cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows and no longer present transfers between cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early application is permitted. We are currently evaluating the potential impact of the adoption of this standard on our financial statements.

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 all of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. For the year ended December 31, 2016, management is required to make an assessment of the effectiveness of our internal control over financial reporting as required by Section 404(a) of the Sarbanes-Oxley Act, as further described in Item 9A of this Annual Report on Form 10-K. The Dodd-Frank Wall Street Reform and Consumer Protection Act exempts non-accelerated filers from compliance with Section 404(b) of the Sarbanes-Oxley Act, which relates to the independent auditor's attestation on the effectiveness of the issuer's internal control over financial reporting. As such, 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 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

Disclosure 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, 2016, 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.

Management's Report on Internal Control Over Financial Reporting

In accordance with Section 404(a) of the Sarbanes-Oxley Act, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). In adopting the 2013 Framework, management assessed the applicability of the principles within each component of internal control and determined whether or not they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our principal executive officer and our principal financial officer, concluded that, as of December 31, 2016, our internal control over financial reporting was effective at the reasonable assurance level based on those criteria.

This annual report does not include 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 2017 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 2017 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 2017 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 2017 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 2017 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:

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 14, 2017

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 14, 2017
/s/ Mariam E. Morris **Mariam E. Morris**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2017
/s/ Thomas Aasen **Thomas Aasen**	Director	March 14, 2017
/s/ Eugene A. Bauer **Eugene A. Bauer**	Director	March 14, 2017
/s/ Isaac Blech **Isaac Blech**	Director	March 14, 2017
/s/ Phil Gutry **Phil Gutry**	Director	March 14, 2017
/s/ Magnus Persson **Magnus Persson**	Director	March 14, 2017

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, 2016 and 2015, 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, 2016. 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, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring net losses, has generated negative cash flows from operations, has an accumulated deficit at December 31, 2016 and current cash and cash equivalents at December 31, 2016 that will not be sufficient to meet its anticipated cash requirements through a period of one year after the date that the financial statements are issued. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Baltimore, Maryland
March 14, 2017

CERECOR INC.

Balance Sheets

	December 31,	
	2016	**2015**
Assets		
Current assets:		
Cash and cash equivalents	$ 5,127,958	$ 21,161,967
Grants receivable	132,472	—
Prepaid expenses and other current assets	391,253	401,550
Restricted cash—current portion	11,111	58,832
Total current assets	5,662,794	21,622,349
Restricted cash, net of current portion	62,828	—
Property and equipment, net	43,243	35,216
Total assets	$ 5,768,865	$ 21,657,565
Liabilities and stockholders' equity		
Current liabilities:		
Current portion of long term debt, net of discount	$ 2,353,667	$ 3,208,074
Accounts payable	1,010,209	678,109
Accrued expenses and other current liabilities	942,435	1,885,458
Warrant liability	5,501	27,606
Unit purchase option liability	51	50,571
Total current liabilities	4,311,863	5,849,818
Long term debt, net of current portion and discount	—	2,353,482
Other long term liabilities	1,250,000	370,538
Total liabilities	5,561,863	8,573,838
Stockholders' equity (deficit):		
Preferred stock—$0.001 par value; 5,000,000 and zero shares authorized at December 31, 2016 and 2015, respectively; zero shares issued and outstanding at December 31, 2016 and 2015	—	—
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2016 and 2015; 9,434,141 and 8,650,143 shares issued and outstanding at December 31, 2016 and 2015, respectively	9,434	8,650
Additional paid-in capital	70,232,651	66,638,557
Accumulated deficit	(70,035,083)	(53,563,480)
Total stockholders' equity	207,002	13,083,727
Total liabilities and stockholders' equity	$ 5,768,865	$ 21,657,565

See accompanying notes to financial statements.

CERECOR INC.

Statements of Operations

	Year Ended December 31,		
	2016	**2015**	**2014**
Grant revenue	$ 1,152,987	$ —	$ —
Operating expenses:			
Research and development	10,149,879	6,587,183	12,240,535
General and administrative	7,083,155	4,422,764	4,875,030
Loss from operations	(16,080,047)	(11,009,947)	(17,115,565)
Other income (expense):			
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	72,625	1,313,049	2,266,161
Interest income (expense), net	(464,181)	(793,205)	(1,206,187)
Total other income (expense)	(391,556)	519,844	1,059,974
Net loss	$ (16,471,603)	$ (10,490,103)	$ (16,055,591)
Net loss attributable to common stockholders	$ (16,471,603)	$ (10,490,103)	$ (3,521,153)
Net loss per share of common stock, basic and diluted	$ (1.87)	$ (4.71)	$ (5.48)
Weighted-average shares of common stock outstanding, basic and diluted	8,830,396	2,226,023	642,052

See accompanying notes to financial statements.

CERECOR INC.

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

For the Period from January 1, 2014 to December 31, 2016

	Series A, A-1 and B convertible preferred stock		Stockholders' Equity (Deficit)				
			Common stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity (deficit)
Balance, January 1, 2014	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)
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
Issuance of common stock from sale of shares under common stock purchase agreement, net of offering costs	—	—	763,998	764	1,899,223		1,899,987
Shares purchased through employee stock purchase plan	—	—	20,000	20	(20)	—	—
Stock-based compensation	—	—	—	—	1,694,891	—	1,694,891
Net loss	—	—	—	—	—	(16,471,603)	(16,471,603)
Balance, December 31, 2016	—	$ —	9,434,141	$ 9,434	$ 70,232,651	$ (70,035,083)	$ 207,002

See accompanying notes to financial statements.

CERECOR INC.

Statements of Cash Flows

	Year Ended December 31,		
	2016	**2015**	**2014**
Operating activities			
Net loss	$ (16,471,603)	$ (10,490,103)	$ (16,055,591)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	26,856	23,508	28,943
Loss on disposition of assets	—	—	17,806
Stock-based compensation expense	1,694,891	394,748	1,086,581
Write off of deferred public offering costs	—	—	1,064,106
Non-cash interest expense	162,270	293,748	989,258
Change in fair value of warrant liability, unit purchase option liability and investor rights obligation	(72,625)	(1,313,049)	(2,266,161)
Changes in assets and liabilities:			
Grant receivable	(132,472)	—	—
Prepaid expenses and other assets	22,047	(41,243)	353,973
Restricted cash	(15,107)	116,666	(498)
Accounts payable	332,100	(268,709)	(708,366)
Accrued expenses and other liabilities	(119,495)	1,121,054	(28,400)
Net cash used in operating activities	(14,573,138)	(10,163,380)	(15,518,349)
Investing activities			
Purchase of property and equipment	(34,883)	(19,984)	(19,502)
Net cash used in investing activities	(34,883)	(19,984)	(19,502)
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 B convertible preferred stock and common stock warrants, net of offering costs	—	—	14,584,307
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	—
Proceeds from sale of shares under common stock purchase agreement	2,003,182	—	—
Principal payments on term debt	(3,314,225)	(1,811,744)	—
Payment of offering costs	(114,945)	(2,269,171)	(365,253)
Net cash provided by (used in) financing activities	(1,425,988)	19,602,982	23,858,720
Increase (decrease) in cash and cash equivalents	(16,034,009)	9,419,618	8,320,869
Cash and cash equivalents at beginning of period	21,161,967	11,742,349	3,421,480
Cash and cash equivalents at end of period	$ 5,127,958	$ 21,161,967	$ 11,742,349
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 348,888	$ 568,299	$ 173,514
Supplemental disclosures of non-cash financing activities:			
Accrued deferred financing costs	$ 81,832	$ —	$ —
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.

CERECOR INC.

Notes to Financial Statements

As of and for the Years Ended December 31, 2016 and 2015

1. Business

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, business planning and raising capital.

Liquidity - Going Concern

The Company's financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should the Company be unable to continue to fund its operations. The Company has not generated any product revenues and has not yet achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and if achieved, could be sustained on a continuing basis.

The Company has incurred recurring operating losses since inception. For the year ended December 31, 2016, the Company incurred a net loss of $16.5 million and generated negative cash flows from operations of $14.6 million. As of December 31, 2016, the Company had an accumulated deficit of $70.0 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 preclinical programs, business development and its organizational infrastructure. 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 further offerings of equity or debt securities, non-dilutive financing arrangements such as federal grants, collaboration agreements or out-licensing arrangements, and to explore strategic alternatives such as an acquisition, merger, or business combination. In the long term, the Company plans to meet its capital requirements through 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, that the Company's exploration of strategic alternatives will result in any such transaction, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow. If the Company fails to raise capital or enter into such arrangements or transactions in the short term, it will have to significantly delay, scale back or discontinue the development of one or more of its product candidates or cease its operations altogether. The Company currently anticipates that current cash and cash equivalents will be sufficient to meet its anticipated cash requirements well into the second quarter of 2017. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year of the date that our financial statements were issued.

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, 2016, 2015 and 2014.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The carrying amounts reported in the balance sheets for cash and cash equivalents are valued at cost, which approximates their fair value.

Restricted Cash

During 2013, the Company entered into a lease for office space for its principal offices in Baltimore, Maryland. The Company 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 was supported by funds that were invested in a certificate of deposit. Provided there was no event of default by the Company, the Company requested 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, which occurred in the fourth quarter of 2016, the Company deposited with the landlord the sum of $13,000 as a security deposit. This amount is recorded as restricted cash, net of current portion on the balance sheet at December 31, 2016.

In the third quarter of 2016, the Company entered into a bank services pledge agreement with Silicon Valley Bank. In exchange for receiving business credit card services from Silicon Valley Bank, the Company deposited $50,000 as collateral with Silicon Valley Bank. This amount will remain deposited with Silicon Valley Bank for the duration the business credit card services are used by the Company and is recorded as restricted cash, net of current portion on the balance sheet at December 31, 2016.

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.

Grant Revenue Recognition

The Company recognizes grant revenue when there is (i) reasonable assurance of compliance with the conditions of the grant and (ii) reasonable assurance that the grant will be received. In April 2016, the Company received a research and development grant from the National Institute on Drug Abuse ("NIDA") at the National Institutes of Health ("NIH") to provide additional resources for the period of May 2016 through April 2017 for the Company's now completed Phase 2 clinical trial for CERC-501, "*A Randomized, Double-Blind, Placebo-Controlled, Crossover Design Study of CERC-501 in a Human Laboratory Model of Smoking Behavior.*" The amount of the NIDA award was $1.02 million. Additionally, in July 2016, the Company received a research and development grant from the National Institute on Alcohol Abuse and Alcoholism ("NIAAA") at the NIH to provide additional resources for the period of July 2016 through June 2017 to progress the development of CERC-501 for the treatment of alcohol use disorder. The amount of the NIAAA award was $1.0 million. The Company recognizes revenue under grants in earnings on a systemic basis in the period the related expenditures for which the grants are intended to compensate are incurred. As such, the Company recognized revenue in the amounts of $1.02 million and $132,000 for the year ended December 31, 2016 for the NIDA award and NIAAA award, respectively. As of December 31, 2016, the Company had received the full $1.02 million of the revenue earned under the NIDA award.

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, 2016, the Company does not believe any material uncertain tax positions are present.

Stock-Based Compensation

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 measures the options at their fair value on the date at which the related service is complete. Expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to the completion of the service, the fair value of the awards is remeasured using the then current fair market value of the Company's common stock and updated assumptions in the Black-Scholes option pricing model.

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, 2016 and December 31, 2015, 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.

Recently Adopted Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* The amendments in this update explicitly require a company's management to assess an entity's ability to continue as a going concern within one year after the date the financial statements are issued, and to provide related footnote disclosures in certain circumstances. The new standard is effective in the first annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The new guidance was adopted by the Company in the fourth quarter of 2016. The adoption of this guidance did not impact the Company's financial position, results of operations or cash flows, nor did it significantly impact the Company's disclosures regarding the assessment of its ability to continue as a going concern within one year of the date that our financial statements were issued.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue From Contracts With Customers* ("ASU 2014-09"). Pursuant to this update, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, *Revenue From Contracts With Customers (Topic 606)*, which delays the effective date of ASU 2014-09 by one year. As a result, ASU 2014-09 will be effective for annual reporting periods beginning after December 15, 2017 with early adoption permitted for annual reporting periods beginning after December 15, 2016. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)* ("ASU 2016-08") and ASU No. 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing* ("ASU 2016-10"), and in May 2016 the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606), Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"), each of which clarify the guidance in ASU 2014-09 and have the same effective date as the original standard. The Company has not yet completed its determination of the impact of adopting ASU 2014-09, ASU 2016-08, ASU 2016-10, or ASU 2016-12 on the financial statements, although, the impact, if any, is not expected to be significant. The Company expects to adopt the pronouncement on a full retrospective basis on January 1, 2018.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842).* This guidance revises existing practice related to accounting for leases under ASC 840, *Leases* ("ASC 840") for both lessees and lessors. The new guidance in ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability for nearly all leases (other than leases that meet the definition of a short-term lease). The lease liability will be equal to the present value of lease payments and the right-of-use asset will be based on the lease liability, subject to adjustment such as for initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating leases or capital leases. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while capital leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840). The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting.* The guidance is intended to simplify several areas of accounting for share-based compensation, including income tax impacts, classification on the statement of cash flows and forfeitures. The new standard is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early application is permitted. The Company adopted this standard on January 1, 2017 and its adoption will have no impact on its financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash*. The guidance is intended to address the diversity that currently exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The new standard requires that entities show the changes in the total of cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows and no longer present transfers between cash and cash equivalents, restricted cash and restricted cash equivalents on the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its financial statements.

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, 2016, 2015 and 2014:

Net loss per share, basic and diluted calculation:	Year ended December 31, 2016	2015	2014
Net loss	$ (16,471,603)	$ (10,490,103)	$ (16,055,591)
Extinguishment upon modification of Series A and A-1 convertible preferred stock	—	—	12,534,438
Net loss attributable to common stockholders	$ (16,471,603)	$ (10,490,103)	$ (3,521,153)
Weighted-average common shares outstanding	8,830,396	2,226,023	642,052
Net loss per share, basic and diluted	$ (1.87)	$ (4.71)	$ (5.48)

The following outstanding securities at December, 31, 2016, 2015 and 2014 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	December 31, 2016	2015	2014
Series A convertible preferred stock	—	—	31,116,391
Series A-1 convertible preferred stock	—	—	9,074,511
Series B convertible preferred stock	—	—	58,948,735
Stock options	1,849,359	959,188	552,726
Warrants on common stock	7,400,934	7,400,934	681,858
Warrants on preferred stock	—	—	625,208
Investor rights obligation	—	—	53,351,117
Underwriters' unit purchase option	40,000	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, 2016 and 2015, 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 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 $2.4 million as of December 31, 2016 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, 2016 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*	$ 4,758,539	$ —	$ —
Liabilities			
Warrant liability	$ —	$ —	$ 5,501
Unit purchase option liability	—	$ —	$ 51

	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

*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) 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, 2016, include (i) volatility of 100%, (ii) risk free interest rate of 1.65%, (iii) strike price ($8.40), (iv) fair value of common stock ($0.88), and (v) expected life of 3.8 years.

The underwriters' unit purchase option (the "UPO") was issued to the underwriters of the Company's initial public offering ("IPO") in 2015 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, expires 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 valuing the UPO as of December 31, 2016, include (i) volatility range of 65% to 90%, (ii) risk free interest rate range of 0.44% to 1.64%, (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 ($0.88), and (vii) optimal exercise point of immediately prior to the expiration of the underwriters' Class B warrants, which occurs on April 20, 2017. The fair value of underlying equity was the primary driver of the decrease in fair value of the UPO liability from $50,571 as of December 31, 2015 to $51 as of December 31, 2016. This $50,520 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 considered the probability of achieving certain milestones, the entity's cost of capital, the estimated period the rights were to 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 tables presented below are a summary of changes in the fair value of the Company's Level 3 valuations for the warrant liability, unit purchase option liability and investor rights obligation for the years ended December 31, 2016 and 2015:

	Warrant liability	Unit purchase option liability	Investor rights obligation	Total
Balance at December 31, 2015	$ 27,606	$ 50,571	$ —	$ 78,177
Change in fair value	(22,105)	(50,520)	—	(72,625)
Balance at December 31, 2016	$ 5,501	$ 51	$ —	$ 5,552

	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

No other changes in valuation techniques or inputs occurred during the years ended December 31, 2016 and 2015. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the years ended December 31, 2016 and 2015.

5. Property and Equipment

Property and equipment as of December 31, 2016 and 2015 consisted of the following:

	December 31,	
	2016	2015
Furniture and equipment	$ 58,126	$ 34,918
Computers and software	72,808	61,133
Total property and equipment	130,934	96,051
Less accumulated depreciation	(87,691)	(60,835)
Property and equipment, net	$ 43,243	$ 35,216

Depreciation expense was $26,856 and $23,508 for the years ended December 31, 2016 and December 31, 2015, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2016 and 2015 consisted of the following:

	December 31,	
	2016	2015
Compensation and benefits	$ 272,601	$ 1,128,073
Research and development expenses	315,937	464,719
General and administrative	160,116	253,132
Accrued interest	193,781	39,534
Total accrued expenses and other current liabilities	$ 942,435	$ 1,885,458

7. License Agreements

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 ("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 other development and regulatory milestones, including the first commercial sale. Upon commercialization, the Company is obligated to pay Lilly additional milestones and royalties on net sales.

Lilly CERC-611 License

On September 22, 2016, the Company entered into an exclusive license agreement with Lilly pursuant to which the Company received exclusive, global rights to develop and commercialize CERC-611, previously referred to as LY3130481, a potent and selective transmembrane AMPA receptor regulatory proteins (“TARP”) γ-8-dependent α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (“AMPA”) receptor antagonist. The terms of the license agreement provide for an upfront payment of $2.0 million, of which $750,000 was due within 30 days of the effective date of the license agreement, and the remaining balance of $1.25 million is due after the first subject is dosed with CERC-611 in a multiple ascending dose study and is recorded as other long term liabilities on the balance sheet at December 31, 2016. The Company recorded the $2.0 million upfront amount as a research and development expense in the accompanying statement of operations for the year ended December 31, 2016. Additional payments may be due upon achievement of development and commercialization milestones, including the first commercial sale. Upon commercialization, the Company is obligated to pay Lilly milestone payments and a royalty on net sales.

Merck CERC-301 License

In 2013, the Company entered into an exclusive license agreement with Merck & Co., Inc. ("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 year ended December 31, 2013. Additional payments may be due upon achievement of development and regulatory milestones, including the first commercial sale. Upon commercialization of an NR2B product, the Company is obligated to pay Merck additional milestones and royalties on net sales.

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, which was recorded as research and development expense in the year ended December 31, 2013. Additional payments may be due upon the achievement of development and regulatory milestones. Upon commercialization of a COMT product, the Company is required to pay Merck royalties on net sales.

8. Term Loan

In August 2014, the Company received a $7.5 million secured term loan from a finance company. The loan is secured by a lien on the Company's assets, excluding intellectual property, which is 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, notwithstanding adverse results of clinical trials. 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 the interest rate increasing to 8.20%. Effective December 15, 2016, the prime rate as reported by The Wall Street Journal increased an additional 0.25% resulting in an increase to the current interest rate, which was 8.45% as of December 31, 2016. 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, 2016 and 2015:

	December 31, 2016	December 31, 2015
Term loan	$ 2,374,031	$ 5,688,256
Less: debt discount	(20,364)	(126,700)
Term Loan, net of debt discount	2,353,667	5,561,556
Less: current portion, net of debt discount	(2,353,667)	(3,208,074)
Long term debt, net of current portion and debt discount	$ —	$ 2,353,482

Interest expense, which includes amortization of a discount and the accrual of a termination fee, was approximately $489,000 and $800,000 for the years ended December 31, 2016 and 2015, respectively, and is included in interest income (expense), net on the accompanying statements of operations. The Company will make future principal payments of $2,374,031 through the loan's maturity date in August 2017.

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 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 $106,000 and $159,000 during the years ended December 31, 2016 and 2015, respectively. Accretion of the one-time fee was $56,000 and $84,000 during the years ended December 31, 2016 and 2015, 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 accompanying 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 IPO. 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, 2016, 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.

Common Stock

IPO

On October 20, 2015, the Company closed its IPO of its units. 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).

The Aspire Capital Transaction

On September 8, 2016, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital"), pursuant to which Aspire Capital committed to purchase up to an aggregate of $15.0 million of shares of the Company's common stock over the 30-month term of the Purchase Agreement. Under the Purchase Agreement, on any trading day selected by the Company on which the closing price of the Company's common stock exceeds $0.50, the Company may, in its sole discretion, present a purchase notice directing Aspire Capital to purchase up to 50,000 shares of common stock per day, up to $15.0 million of the Company's common stock in the aggregate at a per share price calculated by references to the prevailing market price of the Company's common stock. Upon execution of the Purchase Agreement, the Company issued and sold to Aspire Capital 250,000 shares of common stock at a price per share of $4.00, for gross proceeds of $1.0 million, and concurrently entered into a registration rights agreement with Aspire Capital registering the shares of the Company's common stock that have been and may be issued to Aspire Capital under the Purchase Agreement. Additionally, as consideration for Aspire Capital entering into the Purchase Agreement, the Company issued 175,000 shares of common stock as a commitment fee. The net proceeds of the Aspire Capital transaction, after offering expenses, to the Company were approximately $1.9 million for the year ended December 31, 2016. As of December 31, 2016, the Company had sold 763,998 shares of common stock to Aspire Capital under the Purchase Agreement. Subsequent to December 31, 2016, the Company sold an additional 965,165 shares of common stock to Aspire Capital under the terms of the Purchase Agreement for gross proceeds of approximately $789,000. As of the date of this Annual Report on Form 10-K, the Company may not issue additional shares of common stock to Aspire Capital under the Purchase Agreement unless shareholder approval to issue additional shares is obtained.

The Maxim Group Equity Distribution Agreement

On January 27, 2017, the Company entered into an Equity Distribution Agreement with Maxim Group LLC ("Maxim"), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Maxim, up to $12,075,338 in shares of its common stock. The Company has no obligation to sell any of the Shares, and may at any time suspend offers under the Equity Distribution Agreement.

As of the date of this Annual Report on Form 10-K, the Company had sold 345,653 shares of its common stock through Maxim under the Equity Distribution Agreement for gross proceeds of $287,000 and may sell up to an additional $11,788,182 of shares of its common stock. This calculation will be updated immediately after we file this Annual Report on Form 10-K and we expect that the amount of securities we will be able to sell under the registration statement on Form S-3 thereafter will be approximately $3.3 million.

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.

Common Stock Warrants

At December 31, 2016, 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		

*Accounted for as a liability instrument (see Note 4)

Warrants Issued to Term Loan Lender

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

2016 Equity Incentive Plan

On April 5, 2016, the Company's board of directors adopted the 2016 Equity Incentive Plan (the "2016 Plan") as the successor to the 2015 Omnibus Plan (the "2015 Plan"). The 2016 Plan was approved by the Company's stockholders and became effective on May 18, 2016 (the "2016 Plan Effective Date").

As of the 2016 Plan Effective Date, no additional grants will be made under the 2015 Plan or the 2011 Stock Incentive Plan (the "2011 Plan"), which was previously succeeded by the 2015 Plan effective October 13, 2015. Outstanding grants under the 2015 Plan and 2011 Plan will continue according to their terms as in effect under the applicable plan.

Upon the 2016 Plan Effective Date, the 2016 Plan reserved and authorized up to 600,000 additional shares of common stock for issuance, as well as 464,476 unallocated shares remaining available for grant of new awards under the 2015 Plan. During the term of the 2016 Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, beginning in 2017, by an amount equal to 4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. As of December 31, 2016, there were 666,069 shares available for future issuance under the 2016 Plan.

For stock options granted to employees and non-employee directors, the estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the individuals' service periods, which is the period in which the awards vest. For stock options issued to non-employees, the Company measures the options at their fair value on the date at which the related service is complete. Expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to the completion of the service, the fair value of the awards is remeasured using the then current fair market value of the Company's common stock and updated assumptions in the Black-Scholes option pricing model. Stock-based compensation expense recognized for the years ending December 31, 2016 and 2015 was as follows:

	Year Ended December 31,	
	2016	2015
Research and development	$ 141,247	$ 67,021
General and administrative	1,553,644	327,727
Total stock-based compensation	$ 1,694,891	$ 394,748

During the first quarter of 2016, the Company modified stock options of its former chief executive officer by extending the life of the awards, which were set to expire in March 2016, to coincide with their original life. This modification resulted in the recording of $781,266 of compensation expense, which is included in general and administrative expenses for the year ended December 31, 2016 in the accompanying statement of operations.

A summary of option activity for the years ended December 31, 2016 and 2015 is as follows:

	Options Outstanding			
	Number of shares	Weighted-average exercise price	Grant date fair value of options granted	Weighted average remaining contractual term (in years)
Balance, January 1, 2015	552,726	$ 9.17		
Granted	523,390	$ 6.31	$ 1,467,886	
Forfeited	(116,928)	$ 8.60		
Balance, December 31, 2015	959,188	$ 7.68		
Granted	915,242	$ 3.35	$ 2,155,234	
Forfeited	(25,071)	$ 5.04		
Balance, December 31, 2016	1,849,359	$ 5.57		8.44
Vested and expected to vest at December 31, 2016	1,849,359	$ 5.57		8.44
Exercisable at December 31, 2016	791,251	$ 7.55		7.24

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, 2016, 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, 2016, 2015 and 2014 was $0.4 million, $0.7 million and $1.3 million, respectively. The per-share weighted-average grant date fair value of the options granted during 2016, 2015 and 2014 was estimated at $2.35, $2.80 and $2.24, respectively.

The assumptions used to determine the grant date fair value of stock options granted to employees and non-employee directors are as follows:

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.01% — 1.93%	1.64% — 1.97%	0.85% — 1.97%
Expected term of options (in years)	5.0 — 6.25	5.0 — 6.25	5.00 — 6.25
Expected stock price volatility	80% — 100.0%	70.0%	70.0%
Expected annual dividend yield	—%	—%	—%

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, 2016, there was approximately $2,047,800 of total unrecognized compensation expense related to unvested options granted under the Plan to be recognized as follows:

Year ending December 31,	
2017	$ 815,654
2018	766,151
2019	357,279
2020	108,716
	$ 2,047,800

Employee Stock Purchase Plan

On April 5, 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan (the "ESPP"). The ESPP was approved by the Company's stockholders and became effective on May 18, 2016 (the "ESPP Effective Date").

Under the ESPP, eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the administrator. The ESPP is administered by the compensation committee of the Company's board of directors. Under the ESPP, eligible employees may purchase stock at 85% of the lower of the fair market value of a share of the Company's common stock (i) on the first day of an offering period or (ii) on the purchase date. Eligible employees may contribute up to 15% of their earnings during the offering period. The Company's board of directors may establish a maximum number of shares of the Company's common stock that may be purchased by any participant, or all participants in the aggregate, during each offering or offering period. Under the ESPP, a participant may not accrue rights to purchase more than $25,000 of the fair market value of the Company's common stock for each calendar year in which such right is outstanding.

Upon the ESPP Effective Date, the Company reserved and authorized up to 500,000 shares of common stock for issuance under the ESPP. On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP shall automatically increase by a number equal to the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, and (ii) 500,000 shares of the Company's common stock, or (iii) a number of shares of the Company's common stock as determined by the Company's board of directors or compensation committee. As of December 31, 2016, 480,000 shares remained available for issuance.

In accordance with the guidance in ASC 718-50, the ability to purchase shares of the Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized stock-based compensation expense of $70,890 for the year ended December 31, 2016.

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 adjustments for unrecognized income tax benefits. Through December 31, 2016, 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,	
	2016	2015
Deferred tax assets:		
Net operating losses	$ 20,587,955	$ 20,350,451
Research and development credits	1,840,505	1,814,296
Deferred rent	11,902	15,599
Accrued compensation	90,936	438,351

Stock-based compensation	2,169,070	1,500,520
Basis difference in tangible and intangible assets	6,174,163	207,157
Total deferred tax assets	30,874,531	24,326,374
Less valuation allowance	(30,874,531)	(24,326,374)
Net deferred tax asset	$ —	$ —

For the year ended December 31, 2016, the Company increased the valuation allowance by $6.5 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, 2016 the Company had $52.2 million of federal and Maryland state net operating loss ("NOL") carryforwards that will begin to expire in 2031. As of December 31, 2016 the Company had $1.8 million and $57,000 of federal and Maryland state 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,	
	2016	2015
Federal statutory rate	34.00 %	34.00 %
Permanent differences	(0.02)%	(0.02)%
Warrants	0.15 %	4.26 %
State taxes	3.44 %	5.12 %
Research and development credit	2.18 %	2.69 %
Other	— %	0.03 %
Change in valuation allowance	(39.75)%	(46.08)%
Effective income tax rate	— %	— %

12. Commitments and Contingencies

Office Lease

In 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 under the lease amounted to approximately $142,000 for the years ended December 31, 2016 and 2015. Pursuant to the terms of such lease, the Company's future lease obligation is as follows:

Year ending December 31,	
2017	$ 154,845
2018	158,716
	$ 313,561

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 $1.4 million of future services under these agreements as of December 31, 2016, for which amounts have not been accrued as services have not been performed. 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 2016 and 2015. 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, 2016	June 30, 2016	September 30, 2016	December 31, 2016
	(in thousands, except per share data)			
Grant revenue	$ —	$ 650	$ 321	$ 182
Operating expenses:				
Research and development	2,293	2,502	4,582	773
General and administrative	2,649	1,636	1,703	1,095
Change in fair value of warrant liability and unit purchase option liability	(47)	91	(101)	130
Interest income (expense), net	(151)	(127)	(104)	(83)
Net loss	$ (5,140)	$ (3,524)	$ (6,169)	$ (1,639)
Net loss per share of common stock, basic and diluted	$ (0.59)	$ (0.41)	$ (0.70)	$ (0.18)

	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 per share of common stock, basic and diluted	$ (4.98)	$ (4.48)	$ (1.06)	$ (0.53)

14. Subsequent Events

On January 27, 2017, the Company entered into an Equity Distribution Agreement with Maxim, pursuant to which the Company may offer and sell shares of its common stock through Maxim. As of the date of this Annual Report on Form 10-K, the Company had sold 345,653 shares of its common stock through Maxim under the Equity Distribution Agreement for gross proceeds of $287,000. Refer to Note 9 for additional information on the Equity Distribution Agreement.

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).
4.14	Registration Rights Agreement, dated as of September 8, 2016, by and between Aspire Capital Fund, LLC and Cerecor Inc. (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on September 12, 2016).
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 (incorporated by reference to Exhibit 10.11 to the Annual Report on Form 10-K filed on March 23, 2016).
10.12 +	Separation Agreement by and between Cerecor Inc. and Blake Paterson, effective January 9, 2016 (incorporated by reference to Exhibit 10.12 to the Annual Report on Form 10-K filed on March 23, 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 (incorporated by reference to Exhibit 10.17 to the Annual Report on Form 10-K filed on March 23, 2016).
10.18 +	Cerecor Inc. 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on May 20, 2016).
10.19 +	Cerecor Inc. 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on May 20, 2016).
10.20	Common Stock Purchase Agreement, dated as of September 8, 2016, by and between Aspire Capital Fund, LLC and Cerecor Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 12, 2016).
10.21 #	Exclusive License Agreement, dated as of September 22, 2016, by and between Cerecor Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on November 8, 2016).
10.21.1	Addendum to Exclusive License Agreement, dated as of October 13, 2016, by and between Cerecor Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 10.1.1 to the Quarterly Report on Form 10-Q filed on November 8, 2016).
10.22	Equity Distribution Agreement, dated as of January 27, 2017, by and between Cerecor Inc. and Maxim Group LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 27, 2017).
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.

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Exhibit 21.1

List of Subsidiaries

None.

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Form (Form S-8 No. 333-207949) pertaining to the 2015 Omnibus Incentive Compensation Plan,

(2) Registration Statement on (Form S-8 No. 333-211490) pertaining to the 2016 Equity Incentive Plan

(3) Registration Statement on (Form S-8 No. 333-211491) pertaining to the 2016 Employee Stock Purchase Plan

(4) Registration Statement on (Form S-1 No. 333-211491) as filed on September 16, 2016

(5) Registration Statement on (Form S-3 No. 333-214507) as filed on November 8, 2016

of our report dated March 14, 2017, with respect to the financial statements of Cerecor Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Baltimore, Maryland
March 14, 2017

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Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) 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
    d) 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 14, 2017

/s/ Uli Hacksell

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

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Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) 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
    d) 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 14, 2017

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

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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, 2016 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 14, 2017	By:	/s/ Uli Hacksell
	Name:	**Uli Hacksell**
	Title:	**Chief Executive Officer** **(Registrant's Principal Executive Officer)**
Date: March 14, 2017	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.