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CERECOR INC. (A Development Stage Entity)

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As confidentially submitted to the Securities and Exchange Commission on December 20, 2013.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Cerecor Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**45-0705648**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

400 E. Pratt Street, Suite 606
Baltimore, Maryland 21202
(410) 522-8707
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Blake M. Paterson, M.D.
President and Chief Executive Officer
Cerecor Inc.
400 E. Pratt Street, Suite 606
Baltimore, Maryland 21202
(410) 522-8707
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, $0.001 par value per share	$	$

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended, and includes the offering price attributable to shares of common stock that the underwriters have an option to purchase to cover over-allotments, if any.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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

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

SUBJECT TO COMPLETION, DATED , 2014.

PRELIMINARY PROSPECTUS

Shares

Common Stock

This is the initial public offering of our common stock. We are offering shares of common stock. We currently expect the initial public offering price to be between $ and $ per share of common stock.

No public market currently exists for our common stock. We plan to apply to list our common stock on the NASDAQ Capital Market under the symbol "CERC."

Investing in our common stock involves risks. See "Risk Factors" beginning on page 10 of this prospectus.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company disclosure requirements for this prospectus and future filings. See "Prospectus Summary — Implications of Being an Emerging Growth Company" on page 4 of this prospectus.

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

(1) We refer you to "Underwriting" beginning on page 153 of this prospectus for additional information regarding total underwriter compensation.

We have granted the underwriters an option to purchase up to additional shares of common stock to cover over-allotments.

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

The underwriters expect to deliver the shares to purchasers on or about , 2014.

Wells Fargo Securities **JMP Securities**

Needham & Company

Prospectus dated , 2014

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

Through and including , 2014 (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

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

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

PROSPECTUS SUMMARY

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

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

Overview

We are a clinical-stage biopharmaceutical company committed to becoming a leader in the development and commercialization of innovative drugs that address the needs of underserved patients with nervous system disorders. We received fast track designation in November 2013 for our lead clinical product candidate, CERC-301, which is currently in Phase 2 development as an oral, once-a-day, adjunctive antidepressant. We believe CERC-301 will be a first-in-class medication that will cause a significant reduction in depression symptoms in a matter of days, as compared to weeks or months with conventional therapies. In addition, we believe that CERC-301 has the potential to be useful as a treatment for acute suicidality and as monotherapy in major depressive disorder, or MDD, and other neuropsychiatric conditions.

We are also developing product candidates from a proprietary platform of compounds specifically engineered to inhibit an enzyme called catechol-*O*-methyltransferase, or COMT, which we refer to as our COMTi platform. These product candidates are potentially best-in-class and have a mechanism of action with demonstrated human proof of concept in subjects with schizophrenia, Parkinson's disease and various impulse control disorders. In 2014, we intend to select lead candidates from our COMTi platform and to initiate two programs for the treatment of various cognition-related disorders.

Members of our management team and board of directors have previously played key roles in the development or commercialization of successful pharmaceutical products, including the blockbuster neuroscience products Prozac®, Zyprexa®, Lyrica®, Cymbalta® and Neurontin®. We believe our management team's experience enables us to develop and utilize cutting-edge drug development methodologies designed to increase the probability of clinical success by reducing placebo response rates and enhancing efficacy signals in our clinical trials. We believe these methodologies may also accelerate time-to-market and reduce overall development costs for our product candidates.

Product Candidate and Platform

CERC-301

Depression is one of the most common serious medical and psychiatric disorders, with more than 150 million adults worldwide suffering from MDD at any given time, according to a 2003 report by the World Health Organization, or WHO, titled *Investing in Mental Health*. According to the IMS Institute for Healthcare Informatics' 2012 report titled *The Use of Medicines in the United States: Review of 2011,* over 264 million prescriptions totaling $11 billion were filled for depression in the United States in 2011.

Nevertheless, most approved depression therapies are characterized by delayed onset of therapeutic response, high rates of treatment failures, low rates of remission and treatment-limiting side effects.

CERC-301 belongs to a class of compounds known as antagonists, or inhibitors, of the N-methyl-D-aspartate, or NMDA, receptor, a receptor subtype of the glutamate neurotransmitter system that is responsible for controlling neurological adaptation. Multiple recent controlled clinical studies have provided evidence that NMDA receptor antagonists can have significant antidepressant activity within several days of administration. Efficacy of the class is further supported by the common off-label use of ketamine throughout the United States as a rapid-acting antidepressant in bipolar depression and MDD. Ketamine is an anesthetic that is a non-selective NMDA receptor antagonist, is not registered as an antidepressant and has several significant limitations, including the need for repeated intravenous administration in a clinic and undesirable side effects such as increases in blood pressure and significant psychotomimetic effects, including intoxication and hallucinations. In addition, ketamine is a Schedule III drug and is prone to abuse.

CERC-301 has potential competitive advantages over current treatments because it is orally administered and it selectively blocks the NMDA receptor subunit 2b, or NR2b, which we believe provides rapid and significant antidepressant activity without the adverse side-effect profile of ketamine and other non-selective NMDA receptor antagonists. An October 2012 study published by the National Institute of Mental Health, or NIMH, provides support for the potential competitive advantages of CERC-301 because it demonstrated that CERC-301 had a rapid onset of antidepressant effect in patients with treatment resistant depression without the side effects commonly seen in non-selective NMDA receptor antagonists.

We have begun enrollment in our ongoing Phase 2 study, which we refer to as Clin301-201, a double-blind, placebo-controlled trial in 135 MDD subjects who, despite their current treatment with selective serotonin reuptake inhibitors, or SSRIs, or serotonin-norepinephrine reuptake inhibitors, or SNRIs, are severely depressed and have recently experienced active suicidal ideation. We anticipate study completion and receipt of complete data by year-end 2014. If we achieve the primary endpoint, we plan to apply for breakthrough therapy designation for CERC-301 and we intend to propose to the United States Food and Drug Administration, or the FDA, that this study be deemed an adequate, well-controlled trial for purposes of our future submission of a New Drug Application, or NDA.

In this trial, we are administering CERC-301 once a day as a therapy adjunctive to subjects' current medications. The primary endpoint of this trial is antidepressant effect at seven days as measured by the Hamilton Depression Inventory 17 item scale, or HAMD-17, a scale that is used to measure antidepressant effect in drug registration trials. Key secondary endpoints are maintenance of antidepressant effect at 28 days as measured by the HAMD-17 and the measurement of suicidality throughout the study with the Beck Scale for Suicidal Ideation, a questionnaire that is used to detect and measure the severity of suicidal ideation, at each subject visit. We believe that even achieving antidepressant effect at 28 days will provide significant value and may constitute a basis for marketing approval.

We also are preparing to initiate an inpatient Phase 2 study of CERC-301 in the first half of 2014, in both severely depressed subjects experiencing active suicidality and in healthy volunteers. The study will examine safety and efficacy biomarkers across a broad range of doses in different subject populations. We will also evaluate clinical measures such as reduction of suicidality and improvement of mood. We anticipate study completion and receipt of complete data from this trial by year-end 2014. These results will also guide future studies for other indications, such as the treatment of acute suicidality.

COMTi Platform

Our COMTi platform consists of a library of approximately 2,000 compounds specifically engineered to penetrate the nervous system and to preferentially inhibit COMT in the brain. COMT is

an enzyme that breaks down dopamine and its inhibition has demonstrated applicability in treating certain neuropsychiatric conditions, including schizophrenia, Parkinson's disease and various impulse control disorders. We believe potent, brain-specific COMT inhibitors will selectively increase dopamine levels in the prefrontal cortex, which is the region of the brain that is responsible for verbal learning, working memory, attention tasks and decision making, thereby improving executive function. Moreover, our development efforts are specifically focused on a new generation of potent COMT inhibitors that avoid off-target toxicity and side effects, such as liver toxicity and diarrhea, which are often seen with the previous generation of inhibitors, such as tolcapone and entacapone.

Our Strategy

Our goal is to be a leader in the development and commercialization of innovative drugs that address human nervous system disorders. Our strategic objectives include:

- rapidly advancing the clinical development of CERC-301;
- leveraging our COMTi platform to build a pipeline of product candidates for disease states where impaired executive function is a core symptom;
- establishing specialty segment commercialization and marketing capabilities in the United States;
- establishing collaborations to maximize value; and
- expanding our product candidate portfolio through strategic acquisitions.

Management

Members of our management team have extensive pharmaceutical product development and commercialization experience and they have played key roles in the development or commercialization of Prozac, Zyprexa, Lyrica, Cymbalta and Neurontin, each of which is a neuroscience product that has generated over $1.0 billion of annual revenues. Collectively, our directors and officers have contributed to the submission of numerous Investigational New Drug Applications, or INDs, and nine NDAs to the FDA. The Chairman of our Board, Sol Barer, Ph.D., was previously the Chairman and Chief Executive Officer of Celgene Corporation. Leveraging the experience of our management team, we obtained IND clearance and received fast track designation for CERC-301 from the FDA, initiated a Phase 2 clinical trial of CERC-301 and initiated lead candidate selection activities for the COMTi platform, all within eight months of securing licenses to CERC-301 and the COMTi platform.

Risks Associated with Our Business

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

- we have not received, and we may not receive, regulatory approval for CERC-301 or any other product candidates;
- we have no source of predictable revenue, have incurred significant operating losses since inception, may never become profitable and may incur substantial and increasing net losses for the foreseeable future as we continue development of, seek marketing approvals for and begin to commercialize our product candidates;

- we will likely need to obtain additional funding to continue operations, which may not be available to us on acceptable terms, or at all;
- our success is primarily dependent on the successful development, marketing approval and commercialization of our product candidates, all of which are in early development;
- if clinical trials of our product candidates fail to demonstrate safety and efficacy, we may be unable to obtain marketing approvals and commercialize our product candidates;
- we are subject to marketing approval processes that are lengthy, expensive, time-consuming and unpredictable;
- the third-party coverage and reimbursement status of our product candidates is uncertain, and failure to obtain or maintain adequate coverage and reimbursement for products could limit our ability to market those products and decrease our ability to generate revenue;
- we may be unable to recruit or retain key employees, including our senior management team, which may prevent us from successfully developing and commercializing our product candidates or otherwise implementing our business plan;
- we may not be able to obtain and enforce patent rights or other intellectual property rights that cover our product candidates and that are of sufficient breadth to prevent third parties from competing against us; and
- we depend on the performance of third parties, including contract research organizations and third-party manufacturers.

Our Corporate Information

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

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

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.0 billion in annual revenues, have more than $700.0 million in market value of our capital stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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

THE OFFERING

Common stock offered	shares
Common stock to be outstanding immediately following this offering	shares
Over-allotment option	We have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million, or approximately $ million if the underwriters exercise their over-allotment option in full, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the costs of Phase 2 clinical development of CERC-301, research and development to build our COMTi platform and advance our pipeline of preclinical product candidates, and for working capital and general corporate purposes. See "Use of Proceeds."
Risk Factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed NASDAQ Capital Market symbol	"CERC"

The number of shares of our common stock to be outstanding after this offering is based on 18,000,000 shares of our common stock outstanding as of September 30, 2013, including 200,000 shares of unvested restricted stock, and includes shares of our common stock issuable upon the automatic conversion of all outstanding shares of our convertible preferred stock, including shares of common stock issuable as payment of accrued dividends, upon the closing of this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and assuming that the closing occurred on .

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

- 10,687,375 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2013, at a weighted-average exercise price of $0.28 per share;
- 14,258,810 shares of our common stock issuable upon the exercise of warrants outstanding as of September 30, 2013 at a weighted-average exercise price of $0.94 per share, which warrants will remain outstanding upon the closing of this offering in accordance with their terms;
- 10,736,630 shares of our common stock available for future issuance under our 2011 Stock Incentive Plan as of September 30, 2013; and
- shares of our common stock available for future issuance under our 2014 equity compensation plan, which will become effective upon the closing of this offering.

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

- a for reverse stock split of our common stock effected on , 2014;
- no exercise of the outstanding options or warrants described above;
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock to cover over-allotments;
- the conversion of all outstanding shares of our convertible preferred stock, including shares of common stock issuable as payment of accrued dividends, into an aggregate of shares of our common stock, which will occur automatically upon the closing of this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and assuming that the closing occurred on ;
- the warrants outstanding as of September 30, 2013 to purchase an aggregate of 14,258,810 shares of our common stock will remain outstanding upon the closing of this offering in accordance with their terms at a weighted-average exercise price of $0.94 per share; and
- the amendment and restatement of our certificate of incorporation and bylaws upon the closing of this offering.

SUMMARY FINANCIAL DATA

The following tables set forth our summary financial data for the periods indicated. The following summary financial data for the period from January 31, 2011 (Date of Inception) to December 31, 2011 and for the year ended December 31, 2012 and the selected balance sheet data as of December 31, 2011 and 2012 are derived from our audited financial statements appearing elsewhere in this prospectus, which have been audited by Ernst & Young LLP, our independent registered public accounting firm. The following summary of our statement of operations data for the nine-month periods ended September 30, 2012 and 2013 and the period from January 31, 2011 (Date of Inception) to September 30, 2013 and the balance sheet data as of September 30, 2013 are derived from unaudited financial statements appearing elsewhere in this prospectus.

The financial data for the nine months ended September 30, 2012 and 2013 and as of September 30, 2013, in the opinion of management, includes all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of the financial position and the results of operations of the company for these periods. Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2013.

This summary financial data should be read together with the historical financial statements and related notes to those statements, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations," which are included elsewhere in this prospectus.

	Period from January 31, 2011 (Date of Inception) to December 31, 2011	Year Ended December 31, 2012	Nine Months Ended September 30,		Period from January 31, 2011 (Date of Inception) to September 30, 2013
			2012	2013	
			(unaudited)	(unaudited)	(unaudited)
Statements of Operations Data:					
Grant revenue	$ 209,716	$ 82,760	$ 82,760	$ —	$ 292,476
Operating expenses:					
Research and development	2,818,096	8,476,604	6,719,239	7,054,223	18,348,923
General and administrative	838,056	2,097,105	1,323,172	2,923,070	5,858,231
Total operating expenses	3,656,152	10,573,709	8,042,411	9,977,293	24,207,154
Loss from operations	(3,446,436)	(10,490,949)	(7,959,651)	(9,977,293)	(23,914,678)
Other income (expense), net	(36,743)	1,350	(3,766)	7,537	(27,856)
Net loss	$ (3,483,179)	$ (10,489,599)	$ (7,963,417)	$ (9,969,756)	$ (23,942,534)
Deemed dividend	$ —	$ —	$ —	$ (81,963)	$ (81,963)
Net loss attributable to common stockholders	$ (3,483,179)	$ (10,489,599)	$ (7,963,417)	$ (10,051,719)	$ (24,024,497)
Net loss per share — basic and diluted	$ (0.29)	$ (0.59)	$ (0.45)	$ (0.57)	
Weighted-average shares of common stock outstanding used in computing net loss per share — basic and diluted	11,900,895	17,642,964	17,623,813	17,723,901	
Pro forma net loss per share of common stock — basic and diluted					
Pro forma weighted-average shares of common stock outstanding used in computing pro forma net loss per share — basic and diluted					

The following table presents our summary balance sheet data:

- on an actual basis as of September 30, 2013;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our convertible preferred stock, including shares of common stock issuable as payment of accrued dividends, into an aggregate of shares of our common stock, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and assuming that the closing occurred on ; and
- on a pro forma as adjusted basis to give further effect to our sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

	As of September 30, 2013 (unaudited)		
Balance Sheet Data:	**Actual**	**Pro forma**	**Pro forma as adjusted**
Cash and cash equivalents	$ 6,340,269		
Total assets	$ 7,253,801		
Total liabilities	$ 2,374,684		
Convertible preferred stock	$ 25,687,056		
Total stockholders' deficit	$ (20,807,939)		

RISK FACTORS

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

Risks Related to Our Financial Position and Capital Needs

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

We are a clinical-stage biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate an adequate effect or acceptable safety profile, gain marketing approval and become commercially viable. To date, we have financed our operations primarily through private placements of our common and convertible preferred stock and convertible debt. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses in each period since our inception in 2011. For the period from January 31, 2011 (Date of Inception) to December 31, 2011, the year ended December 31, 2012, and the nine months ended September 30, 2013, we reported a net loss of $3.5 million, $10.5 million and $10.0 million, respectively. As of September 30, 2013, we had an accumulated deficit of $23.9 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development program and from general and administrative costs associated with our operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We commenced active operations in the second quarter of 2011 and our operations to date have included organizing and staffing our company, business planning, raising capital and developing our product candidates and platform. Our lead product candidate, CERC-301, is currently in Phase 2 development and we anticipate study completion and receipt of complete data from our Phase 2 trials by year-end 2014. We have not yet, however, demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

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

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

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

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

Risks Related to Our Business and Industry

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

We intend to invest a significant portion of our efforts and financial resources in the development of our lead product candidate, CERC-301; and we anticipate that we will allocate the majority of the proceeds of this offering toward its development. To date we have not marketed, distributed or sold any products. Our ability to generate revenues is substantially dependent on the development and commercialization of CERC-301. If our clinical development is successful, we plan to submit an NDA seeking approval to commercialize CERC-301 as an adjunctive treatment for depression. We cannot commercialize CERC-301 prior to obtaining marketing approval from the FDA. CERC-301 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 CERC-301 is not approvable. If we do not receive marketing approval for and commercialize CERC-301, we will not be able to generate product revenues in the foreseeable future, or at all.

If, following submission, our NDA 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. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional required trials that we perform and complete to be sufficient.

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

Only one of our product candidates that we intend to commercialize is in clinical development. Preclinical and clinical 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 independently. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on our ability to advance our preclinical product candidates into clinical development. 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, our 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 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, 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 and institutional review boards, or IRBs;
- imposition of a clinical hold 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;
- 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;
- 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;
- adding new investigators and clinical trial sites;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

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

If we are unable to enroll 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 subjects to participate in testing our product candidates as well as completion of required follow-up periods. If subjects are unwilling to participate in our trials because of negative publicity from adverse events in the biotechnology industry or for other reasons, including competitive clinical trials for similar subject populations, the timeline for recruiting subjects, conducting trials and obtaining marketing approval of potential products may be delayed. These delays could result in increased costs, delays in

advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. Many factors affect subject enrollment, including:

- the size and nature of the subject population;
- the number and location of clinical sites we enroll;
- the proximity of subjects to clinical sites;
- perceived risks and benefits of the product candidate under trial;
- competition with other companies for clinical sites or subjects;
- competing clinical trials;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain subject consents;
- ability to monitor subjects adequately during and after the administration of the product candidate;
- risk that enrolled subjects will drop out 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 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, our clinical trials may be delayed. 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 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; and
- 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.

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

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

A key element of our strategy is to leverage and expand our COMTi platform to build a pipeline of product candidates for disease states where impaired executive function is a core symptom, 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. We may not be able to develop COMTi product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree on the design or implementation of our clinical trials, including the methodology used in our studies, our chosen endpoints, our statistical analysis, or our proposed product indication. For instance, the FDA may consider the sequential parallel comparison design that we are utilizing in our ongoing Phase 2 clinical trial of CERC-301 to be novel. Even though another company, Alkermes plc, is also using this design in its drug registration trials, there is no regulatory precedent for approval of a product based upon such a design. The FDA also may not agree with the various depression

and other disease scales and evaluation tools that we are using in our clinical trials to assess the efficacy of our product candidates. Further, the FDA may not agree with our endpoints, such as our seven-day efficacy endpoint in our ongoing Phase 2 trial of CERC-301;

- 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 Phase 1B study of CERC-301 conducted by the National Institute of Mental Health, CERC-301 failed to provide a significant improvement in subjects receiving the compound as compared to those receiving a placebo, as measured by the Montgomery-Asberg Depression Rating Scale, the primary assessment tool. Significant improvements were, however, observed using alternative assessment tools, such as the Hamilton Depression Inventory 17 item scale or the Beck Depression Inventory;
- 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 our lead product candidate, CERC-301, and we plan to seek a breakthrough therapy designation for CERC-301 if we receive positive results from either of our Phase 2 trials. Additionally, if we receive positive results from our full clinical trial program for CERC-301, we plan to seek priority review designation upon filing a marketing application. We may seek a fast track product designation, breakthrough therapy designation and priority review designation for certain of our other product candidates if supported by the results of clinical trials. 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 either 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 decide that the time period for FDA review or approval will not be shortened.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authority. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, our Phase 2 clinical trials for CERC-301 could reveal adverse events, including dose-related increases in blood pressure, palpitations, sleepiness, forgetfulness, headache, dizziness, fatigue, lightheadedness or impaired concentrations. In such an event, 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. 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;
- 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 risk evaluation and mitigation strategy, or REMS, 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 subjects 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; 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.

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, 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. 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 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 that a product of this type is a rapid-acting antidepressant, or RAAD, and indicated that we may therefore be subject to limitations on our ability to label and promote the product as a RAAD upon approval.

In addition, manufacturers of drug products and their facilities, including contracted facilities, are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practice, or cGMP, 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 requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials 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;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including restrictions on marketing 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 require us to 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 and investigations, civil and criminal sanctions by the government, 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 and 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. 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 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.

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

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

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

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

- different regulatory requirements for approval of drugs in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

Our competitors may obtain marketing approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or

commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

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

There are numerous currently approved therapies for treating depression and, consequently, competition in the depression market is intense. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection and non-patent regulatory exclusivity, and others are available on a generic basis. For example, CERC-301 will compete with drugs used as adjunctive therapies such as Abilify, marketed by Otsuka America Pharmaceutical, Inc. and Bristol-Myers Squibb Co.; Seroquel, marketed by AstraZeneca plc, or AstraZeneca; and buproprion, a generic drug. In addition, to our knowledge, there are five competitive programs in development that have an NMDA antagonist mechanism of action similar to CERC-301: eskatamine/s-ketamine, which is in Phase 2 development by Johnson & Johnson, or J&J, and is being developed to be administered as a nasal spray; AZD6765, which is in Phase 2 development by AstraZeneca and is being developed to be administered intravenously; GLYX-13, which is in Phase 2 development by Naurex Inc., or Naurex, and is being developed to be administered intravenously; NRX-1074, which is in early Phase 1 development by Naurex, and is being developed to be administered orally; and EVT 103, which is in preclinical development by Evotec AG and J&J, and is being developed to be administered orally.

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

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

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- how quickly and effectively we alone, or with a partner, can market and launch any of our product candidates that receive marketing approval;
- the ability to commercialize any of our product candidates that receive marketing approval;
- the price of our products, including in comparison to branded or generic competitors;
- the ability to collaborate with others in the development and commercialization of new products;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates;

- the entry of generic versions of our products onto the market;
- the number of products in the same therapeutic class as our product candidates;
- the ability to secure favorable managed care formulary positions, including federal healthcare program formularies;
- the ability to manufacture commercial quantities of any of our product candidates that receive marketing approval; and
- acceptance of any of our product candidates that receive marketing approval by physicians and other healthcare providers.

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

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

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

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

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

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products will be available from government authorities, 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 drug purchases 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 could 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 could 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.

Notably, a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the full effect of the Affordable Care Act, the new law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 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 Supply Chain 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 the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. 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 notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, 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 $5.0 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 customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from participation in federal healthcare programs, contractual damages, 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. Actions resulting in violations of these laws may result in civil and criminal liability, as well as exclusion from participation in federal healthcare programs. Restrictions under applicable federal and state healthcare 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, 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;

- the criminal federal False Claims Act imposes criminal fines or imprisonment against individuals or entities who make or present of 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 U.S. Department of Health and Human Services 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 applicable manufacturers and applicable group purchasing organizations to report annually to the U.S. Department of Health and Human Services ownership and investment interests held by physicians (as defined above) and their immediate family members;

- 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; and

- analogous state and foreign laws and regulations, 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; and state and foreign laws that govern the privacy and security of health 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. 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 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 that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is 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.

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 our management, scientific and medical personnel, as well as our board members. The loss of the services of any of these individuals 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 any of these individuals, we may not be able to find suitable replacements on a timely basis, or at all, and our business would likely be harmed as a result. We do not maintain "key man" insurance policies on the lives of these individuals 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, 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, consultants and vendors may engage in fraudulent or other illegal activity. Misconduct by these

parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, (2) manufacturing standards, (3) federal and state healthcare fraud and abuse laws and regulations or (4) laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. The improper use of information obtained in the course of clinical trials could also result in significant legal sanctions and serious harm to our reputation. In addition, federal procurement laws and regulations impose substantial penalties for misconduct in connection with government contracts and require contractors to maintain a code of business conduct and ethics. In contemplation of this offering, we will adopt a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant criminal and civil fines, penalties, or other sanctions, including exclusion from participation in federal healthcare programs.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. In contemplation of this offering, we will adopt an Insider Trading Policy, but despite the adoption of such policy, we may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

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

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

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

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

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

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

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

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; 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 and our CROs are required to comply with cGCP 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 cGCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCP 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. 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 cGCP requirements. In addition, we must conduct our clinical trials with product produced under applicable cGMP 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 are not our employees, and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. These CROs 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 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. 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 cGMP requirements, for manufacture of both active drug substances and finished drug products. 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. 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 cGMP 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 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.

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. A third party may hold intellectual property, including patent rights that are important or necessary to the development of our products. As a result, we are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. If we fail to comply with the obligations under these agreements, including payment and diligence terms, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. 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.

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

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

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

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

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non- exclusive, thereby giving our

competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In addition, we may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property 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 U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and

specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Risks Related to this Offering and Ownership of Our Common Stock

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

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

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

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

- the development status of our product candidates, and when any of our product candidates receive marketing approval;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our failure to commercialize our product candidates, if approved;
- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;

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

- the development and sustainability of an active trading market for our common stock;
- future sales of our common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles; and
- general economic, industry and market conditions.

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

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

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

- Phase 2 clinical development of CERC-301;
- research and development under our COMTi platform and advance our pipeline of preclinical product candidates, including the selection of lead candidates and to initiate two programs; and
- working capital and other general corporate purposes.

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

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

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

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

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

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

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

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company." For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting 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 Securities and Exchange Commission, or SEC, which may make it more difficult for investors and securities analysts to evaluate our company. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less

attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of common stock based on the number of shares outstanding as of , assuming (i) no exercise of the underwriters' over-allotment option; and (ii) the conversion of all outstanding shares of our convertible preferred stock into shares of common stock immediately prior to the closing of this offering assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and that the closing occurred on . shares will be eligible for resale on the public market immediately, and of the shares may be sold after the expiration of lock-up agreements at least 180 days after the date of this prospectus pursuant to Rule 144 or Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, unless held by an affiliate of ours, as more fully described in the section entitled "Shares Eligible for Future Sale."

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

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

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC, the NASDAQ Capital Market and other applicable securities rules and regulations imposed on public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss.

For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

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

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

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

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

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and 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.

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

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

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- 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 common stock.

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

USE OF PROCEEDS

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

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

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

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. As of September 30, 2013, we had cash and cash equivalents of $6.3 million. We plan to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

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

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

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to complete Phase 2 clinical development of CERC-301 and identify our lead preclinical product candidates and begin preclinical work with respect to our COMTi platform. It is possible that we will not achieve the progress that we expect with respect to CERC-301 and our COMTi platform because the actual costs and timing of development and marketing approval are difficult to predict and are subject to substantial risks and delays.

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

DIVIDEND POLICY

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

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2013:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of shares of our common stock, including shares of common stock issuable as payment of accrued dividends, upon the closing of this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and assuming that the closing occurred on ; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

	As of September 30, 2013		
	Actual	Pro forma	Pro forma as adjusted
	(in thousands, except share and per share data) (unaudited)		
Cash and cash equivalents	$ 6,340	$	$
Liabilities:			
Total liabilities	2,375		
Convertible Preferred Stock:			
Series A convertible preferred stock, $0.001 par value; 31,500,000 shares authorized, 31,116,391 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	19,857		
Series A-1 convertible preferred stock, $0.001 par value; 20,000,000 shares authorized, 9,074,511 shares issued and outstanding, actual; no shares designated, issued or outstanding, pro forma and pro forma as adjusted	5,830		
	25,687		
Stockholders' deficit:			
Common stock, $0.001 par value; 167,000,000 shares authorized, 18,000,000 shares issued and outstanding, actual; shares authorized, and shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	18		
Preferred stock, par value $0.001; no shares authorized, issued and outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Additional paid in capital	3,117		
Accumulated deficit	(23,943)		
Total stockholders' deficit	(20,808)		
Total capitalization	$ 7,254	$	$

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

The table above does not include:

- 10,687,375 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2013 at a weighted-average exercise price of $0.28 per share;
- 14,258,810 shares of our common stock issuable upon the exercise of warrants outstanding as of September 30, 2013 at a weighted-average exercise price of $0.94 per share, which warrants are expected to remain outstanding upon the closing of this offering;
- 10,736,630 shares of our common stock available for future issuance under our 2011 Stock Incentive Plan as of September 30, 2013; and
- shares of our common stock available for future issuance under our 2014 equity compensation plan, which will become effective upon the closing of this offering.

DILUTION

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

The historical net tangible book value of our common stock as of was $ million, or $ per share of our common stock, based on shares of our common stock outstanding as of .

The pro forma net tangible book value of our common stock as of was $ million, or $ per share of our common stock, and represents our historical net tangible book deficit as of after giving effect to the conversion of all of our outstanding convertible preferred stock into an aggregate of shares of our common stock, including shares of common stock issuable as payment of accrued dividends, upon the closing of this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and assuming that the closing occurred on .

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

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

Assumed initial public offering price per share	$
Historical net tangible book value per share as of	
Pro forma increase in net tangible book value (deficit) per share attributable the conversion of outstanding convertible preferred stock	
Pro forma net tangible book value (deficit) per share before this offering	
Pro forma increase in net tangible book value (deficit) per share attributable to new investors purchasing common stock in this offering	
Pro forma as adjusted net tangible book value (deficit) per share after this offering	
Dilution per share to new investors purchasing common stock in this offering	$

A $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value by $ million or by $ per

share and the dilution to new investors in this offering by $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

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

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

	Shares Purchased		Total Consideration		
(in thousands, except per share amounts)	**Number**	**Percentage**	**Amount**	**Percentage**	**Average Price Per Share**
Existing stockholders		%	$	%	$
New investors					
Total		%	$	%	

The number of shares of our common stock outstanding immediately following this offering is based on 18,000,000 shares of our common stock outstanding as of September 30, 2013, including 200,000 shares of unvested restricted stock, and giving effect to the pro forma conversion of our convertible preferred stock described above. This number excludes:

- 10,687,375 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2013 at a weighted-average exercise price of $0.28 per share;
- 14,258,810 shares of our common stock issuable upon the exercise of warrants outstanding as of September 30, 2013 at a weighted-average exercise price of $0.94 per share, which warrants are expected to remain outstanding upon the closing of this offering;

- 10,736,630 shares of our common stock available for future issuance under our 2011 Stock Incentive Plan as of September 30, 2013; and

- shares of our common stock available for future issuance under our 2014 equity compensation plan, which will become effective upon the closing of this offering.

To the extent that outstanding stock options are subsequently exercised, there will be further dilution to new investors. If all outstanding options as of September 30, 2013 had been exercised, assuming the treasury stock method, the pro forma net tangible book value per share as of September 30, 2013 (calculated on the basis of the assumptions set forth above) would have been approximately $ million, or $ per share of our common stock, and the pro forma as adjusted net tangible book value would have been $ per share, representing dilution in our pro forma adjusted net tangible book value per share to new investors of $.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

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

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

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

- the number of shares of our common stock held by new investors will increase to approximately % of the total number of shares of our common stock outstanding after this offering.

SELECTED FINANCIAL DATA

The following tables set forth our summary financial data for the periods indicated. The following summary financial data for the period from January 31, 2011 (Date of Inception) to December 31, 2011 and for the year ended December 31, 2012 and the selected balance sheet data as of December 31, 2011 and 2012 are derived from our audited financial statements, which have been audited by Ernst & Young LLP, our independent registered public accounting firm, appearing elsewhere in this prospectus. The following summary of our statement of operations data for the nine-month periods ended September 30, 2012 and 2013 and the period from January 31, 2011 (Date of Inception) to September 30, 2013 and the balance sheet data as of September 30, 2013 are derived from our unaudited condensed financial statements appearing elsewhere in this prospectus.

The financial data for the nine months ended September 30, 2012 and 2013 and as of September 30, 2013, in the opinion of management, includes all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of the financial position and the results of operations for these periods. Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 2013.

This summary financial data should be read together with the historical financial statements and related notes to those statements, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations," which are included elsewhere in this prospectus.

	Period from January 31, 2011 (Date of Inception) to December 31, 2011	Year Ended December 31, 2012	Nine Months Ended September 30,		Period from January 31, 2011 (Date of Inception) to September 30, 2013
			2012 (unaudited)	2013 (unaudited)	(unaudited)
Statements of Operations Data:					
Grant revenue	$ 209,716	$ 82,760	$ 82,760	$ —	$ 292,476
Operating expenses:					
Research and development	2,818,096	8,476,604	6,719,239	7,054,223	18,348,923
General and administrative	838,056	2,097,105	1,323,172	2,923,070	5,858,231
Total operating expenses	3,656,152	10,573,709	8,042,411	9,977,293	24,207,154
Loss from operations	(3,446,436)	(10,490,949)	(7,959,651)	(9,977,293)	(23,914,678)
Other income (expense), net	(36,743)	1,350	(3,766)	7,537	(27,856)
Net loss	$ (3,483,179)	$ (10,489,599)	$ (7,963,417)	$ (9,969,756)	$ (23,942,534)
Deemed dividend	$ —	$ —	$ —	$ (81,963)	$ (81,963)
Net loss attributable to common stockholders	$ (3,483,179)	$ (10,489,599)	$ (7,963,417)	$(10,051,719)	$ (24,024,497)
Net loss per share — basic and diluted	$ (0.29)	$ (0.59)	$ (0.45)	$ (0.57)	
Weighted-average shares of common stock outstanding used in computing net loss per share — basic and diluted	11,900,895	17,642,964	17,623,813	17,723,901	
Pro forma net loss per share of common stock — basic and diluted (unaudited)					
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)					

	As of December 31,		As of September 30, 2013
	2011	2012	(unaudited)
Balance Sheet Data:			

Cash and cash equivalents	$ 1,111,200	$ 9,519,661	$ 6,340,269
Total assets	1,286,250	10,019,688	7,253,801
Total liabilities	3,776,100	1,543,794	2,374,684
Convertible preferred stock	—	19,856,632	25,687,056
Total stockholders' deficit	(2,489,850)	(11,380,738)	(20,807,939)

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward looking statements that involve risks, uncertainties and assumptions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in this prospectus.

Overview

We are a clinical-stage biopharmaceutical company committed to becoming a leader in the development and commercialization of innovative drugs that address the needs of underserved patients with nervous system disorders. We received fast track designation in November 2013 for our lead clinical product candidate, CERC-301, which is currently in Phase 2 development as an oral, once-a-day, adjunctive antidepressant. We believe CERC-301 will be a first-in-class medication that will cause a significant reduction in depression symptoms in a matter of days, as compared to weeks or months with conventional therapies. In addition, we believe that CERC-301 has the potential to be useful as a treatment for acute suicidality and as monotherapy in major depressive disorder, or MDD, and other neuropsychiatric conditions.

We also are developing product candidates from a proprietary platform of compounds specifically engineered to inhibit an enzyme called catechol-*O*-methyltransferase, or COMT, which we refer to as our COMTi platform. These product candidates are potentially best-in-class and have a mechanism of action with demonstrated human proof of concept in subjects with schizophrenia, Parkinson's disease and various impulse control disorders. In 2014, we intend to select lead candidates from our COMTi platform and to initiate two programs for the treatment of various cognition-related disorders.

We incorporated in January 2011 and commenced operations in the second quarter of 2011. Since inception, our operations have included organizing and staffing our company, business planning, raising capital and developing our product candidates, CERC-301 and FP01, and the COMTi platform. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. We have incurred losses in each period since our inception. We have financed our operations primarily through private placements of our common and convertible preferred stock and convertible debt. As of September 30, 2013, we had a deficit accumulated during the development stage of $24.0 million. Our net loss was $3.5 million and $10.5 million for the years ended December 31, 2011 and 2012, respectively, and $10.0 million for the nine months ended September 30, 2013. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate any product revenue unless, and until, we, or any collaborator we may enter into any arrangement with, obtain marketing approval for and commercialize our product candidates including CERC-301 and any product candidates developed from our COMTi platform.

We have received aggregate net proceeds of $26.8 million through September 30, 2013 from the sale of our common and convertible preferred stock and convertible debt. In addition, we received $292,000 pursuant to a grant agreement with the National Heart, Lung, and Blood Institute of the National Institute of Health, or NIH. From inception through September 30, 2013, we had incurred approximately $18.3 million of total research and development expenses and approximately $5.9 million of total general and administrative expenses.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek marketing approval for, our product candidates.

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

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

Components of Operating Results

Revenue

To date, we have derived all of our revenue from a research grant from NIH. We expect our revenue to continue to decrease due to the completion of our grant program and we do not currently anticipate any revenue from new grant programs or research collaborations.

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

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred developing, testing and seeking marketing approval for our product candidates. These costs include both external costs and internal research and development costs.

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 development programs;
- allocated facilities, depreciation and other expenses, which include rent and utilities, as well as other supplies; and
- product liability insurance.

We track external costs by discovery program and subsequently by product candidate once a product candidate has been selected for development. We have incurred a total of $18.3 million in research and development expenses from inception through September 30, 2013, with $13.4 million being spent on external costs primarily for FP01, and lesser amounts spent on CERC-301, our COMTi platform and other preclinical programs; the remaining $4.9 million was spent on internal costs, which are predominantly personnel-related costs, and external costs. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development, primarily due to the increased size and duration of the clinical trials. As we advance our product candidates through clinical development, we expect that the amount of our research and development spending allocated to external spending relative to internal spending will continue to grow for the foreseeable future, while our internal research and development spending should grow at a slower and more controlled pace.

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.

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain marketing approval. We may never succeed in achieving marketing approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate, the number of clinical sites included in trials, and the need to add more sites, and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability, market acceptance and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential. A change in the outcome of any of the variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, based on the results of our Phase 2 clinical trials of FP01, expected future development expenses and the addressable market, we have decided to seek a partner for further development and commercialization and not incur additional significant research and development expenses. Additionally, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those which we anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

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

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

Change in Fair Value of Warrant Liability

We have issued warrants for the purchase of our common stock that we have classified as liabilities and remeasure to fair value at each balance sheet date, and we record the changes in the fair value of the warrant liability as other loss. We will remeasure the fair value of the warrant liability immediately prior to the closing of this offering, and the fair value of the warrant liability at that time will be reclassified to additional paid-in capital. Based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, we expect to record a related charge of approximately $ as other expense in our results of operations for the period in which this offering closes. Based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, we expect the fair value of the warrant liability that will be reclassified to additional paid-in capital upon consummation of this offering is $ million.

Other Income (Expense)

Other income (expense) consists of non-cash interest expense related to our convertible note payable, which was converted into Series A convertible preferred stock in March 2012.

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Grant Revenue Recognition

We recognize grant revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectability is reasonably assured. In August 2011, we received a research grant from NIH to assist in the funding of certain research activities from August 2011 through July 2012. The amount of the award was $292,000

and as of December 31, 2011 and 2012, we had recognized revenue in the amounts of $210,000 and $83,000, respectively. We recognize revenue under grants in earnings in the period in which the related expenditures are incurred. As the entire grant was received during 2011 and the research work was not completed until 2012, we recorded deferred revenue as of December 31, 2011.

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 part of the process of preparing our financial statements, we are required to estimate our income taxes. This process involves estimating our actual current tax expense together with assessing temporary differences resulting from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. As of December 31, 2012, we had federal net operating loss carryforwards of $4.0 million, which expire starting in 2031, and federal research and development credit carryforwards of $0.1 million, which expire starting in 2031. We also had state net operating loss carryforwards of $4.0 million, which expire starting in 2031. The Internal Revenue Code contains provisions that may limit the net operating loss and credit carryforwards available to be used in any given year given certain historical changes in the ownership interests of significant stockholders. State NOL and credit carryforwards may be similarly or more stringently limited. At December 31, 2012, we recorded a full valuation allowance against our net deferred tax asset of approximately $5.6 million, as our management believes it cannot at this time conclude that it is more likely than not they will be realized. If we determine in the future that we will be able to realize all or a portion of our net deferred tax asset, an adjustment to the deferred tax valuation allowance would increase net income in the period in which we make such a determination.

Stock-Based Compensation

We account for all stock options issued to employees, consultants and non-employee directors using the Black-Scholes option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative accounting guidance, we re-measure the fair value of non-employee stock-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

We apply the fair value recognition provisions of the Financial Accounting Standards Board, or FASB, Accounting Standards Codification Topic 718, *Compensation — Stock Compensation*, or ASC 718. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. We recognize stock-based compensation expense ratably over the requisite service period, which in most cases is the vesting period of the award. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions.

We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock price, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. As a private company, we do not have sufficient history to estimate the volatility of our common stock price. Therefore, we utilize data from comparable public companies to estimate expected stock price volatility. We selected companies from the biopharmaceutical industry with similar characteristics to us, including those in the early stage of product development and with a therapeutic focus. We intend to continue to consistently apply this process using comparable companies until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

We use the simplified method as prescribed by the Securities and Exchange Commission, or SEC, Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of stock option grants to employees and non-employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows for the year ended December 31, 2012 and for the nine months ended September 30, 2013:

	Year Ended December 31, 2012	Nine Months Ended September 30, 2013
Risk-free interest rate	0.85% – 1.14%	1.14 – 1.90%
Expected term of options (in years)	6.0 – 10.0	6.0 – 10.0
Expected volatility	70.0%	70.0%
Dividend yield	0.0%	0.0%

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Through September 30, 2013, actual forfeitures have not been material.

Stock-based compensation expense totaled $588,000 and $543,000 for the year ended December 31, 2012 and for the nine months ended September 30, 2013, respectively. We record stock-based compensation expense as a component of research and development expenses or general and administrative expenses, depending on the function performed by the optionee. For the year ended December 31, 2012 and the nine months ended September 30, 2013, we allocated stock-based compensation as follows:

	Year Ended December 31, 2012	Nine Months Ended September 30, 2013
	(in thousands)	
Research and development	$ 129	$ 125
General and administrative	459	418
Total	$ 588	$ 543

As of September 30, 2013, we had $1.1 million of total unrecognized stock-based compensation expense, which we expect to recognize over a weighted-average remaining vesting period of approximately 1.56 years. While our stock-based compensation for stock options granted to employees

and non-employees to date has not been material to our financial results, in future periods, our stock-based compensation expense is expected to increase as a result of recognizing our existing unrecognized stock-based compensation for awards that will vest and as we issue additional stock-based awards to attract and retain our employees.

Fair Market Value Estimates

We are required to estimate the fair market value of the common stock underlying our stock-based awards when performing the fair value calculations utilizing the Black-Scholes option pricing model. In the absence of a public trading market for our common stock, the fair market value of the common stock underlying our stock-based awards, which represents the most important factor in determining the value of our stock-based compensation, was determined for each grant date by our board of directors, with input from management. All options to purchase shares of our common stock are intended to be granted with an exercise price per share that is no less than the fair market value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. We determined the fair market value of our common stock using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, *Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the AICPA Practice Guide. In addition, we considered various objective and subjective factors, along with input from management and contemporaneous third-party valuations, to determine the fair market value of our common stock, including:

- external market conditions affecting the biotechnology industry;
- the stock prices of other publicly traded biotechnology companies engaged in lines of business that are the same or similar to ours;
- trends within the biotechnology industry;
- past issuances of our common stock;
- the superior rights and preferences of the convertible preferred stock relative to our common stock at the time of each grant;
- the results of our clinical trials;
- our results of operations and financial position as well as important developments in our operations, most significantly relating to the status of our research and development efforts;
- our ability to pay dividends;
- our stage of development, business strategy and prospects;
- the lack of an active public market for our capital stock; and
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, of our common stock or sale of our company in light of prevailing market conditions.

The per share estimated fair market value of our common stock in the table below represents the determination by our board of directors of the fair market value of our common stock as of the date of grant, taking into consideration the various objective and subjective factors described above, including the conclusions, if applicable, of contemporaneous and retrospective independent third-party valuations of our common stock as discussed below. We computed the per share estimated fair value for stock option grants based on the Black-Scholes option pricing model. In addition, in determining the exercise prices of options granted since January 10, 2012, our board of directors considered the most recent available independent third-party valuations of our common stock, which were prepared as of February 24, 2012 and May 6, 2013, and based its determination in part on such valuations, with the analyses summarized below. The intrinsic value of all outstanding vested and unvested options of

$ million is based on an assumed per share price of $, which is the midpoint of the price range set forth on the cover page of this prospectus, 5,987,375 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2013 and a weighted-average exercise price of $0.25 per share. The following table sets forth information about our stock option grants since January 1, 2012:

Date of Issuance	Number of Shares Underlying Options Granted	Exercise Price per Share	Estimated Fair Market Value per Common Share	Estimated Fair Value of Options per Share
1/10/2012	2,400,000	$ 0.20	$ 0.31	$ 0.22
5/8/2012	5,435,000	$ 0.31	$ 0.31	$ 0.19
8/6/2012	90,000	$ 0.31	$ 0.31	$ 0.19
11/9/2012	900,000	$ 0.31	$ 0.31	$ 0.19
2/5/2013	298,000	$ 0.31	$ 0.31	$ 0.19
8/29/2013	1,139,375	$ 0.32	$ 0.32	$ 0.20

Stock options granted on January 10, 2012, May 8, 2012, August 6, 2012, November 9, 2012 and February 5, 2013.

Our board of directors granted stock options on January 10, 2012, May 8, 2012, August 6, 2012, November 9, 2012 and February 5, 2013. Our board of directors determined that the January 10, 2012 grant had an exercise price of $0.20 per share and the May 8, 2012, August 6, 2012, November 9, 2012 and the February 5, 2103 grants each had an exercise price of $0.31 per share. In determining the appropriate exercise price for the option grants on May 8, 2012, August 6, 2012, November 9, 2012 and February 5, 2013, the board of directors considered the most recent independent third-party valuation of $0.31 per share of common stock as of February 24, 2012 and such other factors as we deemed relevant to the analysis.

In determining the appropriate exercise price for the option grants on January 10, 2012, our board of directors considered various objective and subjective factors we believed were relevant as of the grant date, along with input from management, to determine the fair market value of our common stock, including those factors listed above and further:

- the phase of development of our product candidate;
- that we had only recently commenced operations;
- the material risks related to our business and the industry in which we operate;
- that we were being funded by one of our founding shareholders; and
- that there had not been any independent financing of our company.

In conducting the February 24, 2012 valuation, the independent third party utilized the Option Pricing Method, or OPM, to "back-solve" for an equity value which corresponds to the February 2012 Series A convertible preferred stock financing and then allocates value between common and preferred stock. The offering price for each unit in the Series A convertible preferred stock financing was $0.75, which consisted of one share of Series A convertible preferred stock and a warrant to purchase common stock equal to 25% of the number of shares of Series A convertible preferred stock purchased with an exercise price equal to $1.00 per share. The price per share of convertible preferred stock in the Series A financing was deemed to be fair value because the price was set by willing and informed unrelated parties, neither of whom was forced to transact. The Series A financing was concluded after extensive negotiations in which each party sought to obtain the best price.

The first step was to place a value on the company's common equity relying on OPM to back-solve for an equity value which corresponds to the Series A convertible preferred stock price and then allocate

equity value between common and preferred stock. Traditional valuation methodologies do not account for the value of a junior class of equity when certain other investor classes have a liquidation preference. We believe it is appropriate to consider valuing common equity similar to a call option since a company's common equity could always have value, even if the value of the firm's enterprise value is lower than its liquidation preference, similar to out-of-the-money publicly traded stock options that command value because of the possibility that the value of the underlying asset may increase above the strike price in the remaining life of the call option.

The Black-Scholes option pricing model was utilized to determine the value of the common stock. The Black-Scholes option pricing model gives explicit consideration to the time to expiration, stock volatility, the payment (or lack of payment) of dividends and the level of interest rates. Therefore, the life of a call option, the volatility of the underlying stock (firm value for our purposes), the dividend payout capacity, and the level of interest rates all influence the value of a call option. Assumptions used in the February 24, 2012 valuation were determined as follows:

- the current value per share of common stock was based upon the implied value of the equity from the February 24, 2012 Series A convertible preferred stock financing,
- the exercise price was calculated based on the aggregate liquidation preference of the outstanding Series A convertible preferred stock,
- the expected term was estimated to be one year as that is our estimated time horizon for a subsequent liquidity event,
- the volatility factor of 65% was based on comparable biopharmaceutical companies focused on the discovery, development, and commercialization of pharmaceuticals, and
- the risk-free rate of 0.18% was based on the U.S. Treasury yield with a term commensurate with the expected term of one year.

A discount for lack of marketability of 25% was applied to reach the final valuation of the common stock because, as we are a private company, there are impediments to liquidity, including lack of publicly available information and the lack of a trading market. We determined the discount for lack of marketability based on qualitative factors such as proximity to an IPO, funding risk and progress made on clinical development program.

We concluded that the value of our company remained relatively unchanged from January 10, 2012 to February 5, 2013. This was primarily attributable to the absence of a significant product inflection point, insofar as FP01, our lead asset during that timeframe, was in a Phase 2 clinical trial, and our continued efforts to obtain financing to support our liquidity needs and funding of operating expenses. The specific facts and circumstances considered by our board of directors included the following:

- the status of our development efforts including that the Phase 2 FP01 trial for acute cough did not meet its primary endpoint in October 2012;
- we had principally financed our operations through private placements of preferred stock and debt. The original issuance per unit price of $0.75 for the Series A convertible preferred stock financing remained unchanged throughout our closings in 2012;
- the rights, preferences and privileges of our preferred stock as compared to those of our common stock;
- the lack of liquidity of our common stock as a private company;
- the material risks related to our business and industry;
- external market conditions affecting the life science and biotechnology industry sections;
- the likelihood of achieving a liquidity event for the holders of our common stock and stock options given our stage of development and ownership of only one product candidate; and
- the recent valuation prepared in accordance with methodologies outlined in the Practice Aid.

Stock options granted on August 29, 2013.

Our board of directors granted stock options on August 29, 2013 of $0.32 per common share, with an exercise price of $0.32 per share. In addition to taking into account the third-party valuation from May 6, 2013, our board of directors determined that even though we had in-licensed CERC-301 and rights to the COMTi platform, we did not have the results of our Phase 2 FP01 trial for chronic cough and our August 2013 Series A-1 convertible preferred stock price remained the same as the Series A convertible preferred stock price; therefore, there was no material change in the fair market value of our common stock and thus $0.32 per common share was appropriate.

As of May 6, 2013, we estimated the value of our common stock versus the other classes of stock using the option pricing method, consistent with the methodology noted above in the February 24, 2012 valuation. Changes in assumptions since the February 24, 2012 valuation included changing the expected term to four years based upon updated management's estimates, utilizing a risk-free rate of 0.54% based upon the four year expected term and applying a discount for lack of marketability of 30%.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock, including the contemporaneous valuations. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event, the related company valuations associated with such events, and the determinations of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share applicable to common stockholders could have been significantly different.

Recent Accounting Pronouncements

In June 2011, FASB issued ASU No. 2011-05*, Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income*, or ASU 2011-05. This amendment eliminates the option to present the components of other comprehensive income as part of the statement of stockholders' equity. Instead, comprehensive income must be presented in either a single continuous statement of comprehensive income, which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 was effective for fiscal periods beginning after December 15,

2011, with early adoption permitted. Our retrospective adoption of ASU 2011-05 did not have a significant impact on our financial position, results of operations or cash flows.

In February 2013, FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, or ASU 2013-02. ASU 2013-02 requires companies to present, either in a single note or parenthetically on the face of the financial statements, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. This guidance is effective for annual reporting periods beginning after December 15, 2012. We believe the adoption of this standard will not have a significant impact on our financial position, results of operations or cash flows.

JOBS Act

The JOBS Act contains provisions that, among other things, reduce reporting requirements for an "emerging growth company." As an emerging growth company, we have elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

Internal Control Over Financial Reporting

Assessing our staffing and training procedures to improve our internal control over financial reporting is an ongoing process. We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and are therefore not required to make an assessment of the effectiveness of our internal control over financial reporting. As a result, our management did not perform an evaluation of our internal control over financial reporting as of December 31, 2012. Further, our independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting.

Results of Operations

Comparison of Nine Month Periods Ended September 30, 2013 and 2012

Revenue

We did not recognize any revenue for the nine months ended September 30, 2013. During the nine months ended September 30, 2012, we recognized $83,000 of grant revenue associated with our grant from the NIH.

Research and development

Research and development expenses increased by $335,000, from $6.7 million for the nine months ended September 30, 2012 to $7.1 million for the nine months ended September 30, 2013. This increase was primarily driven by a $646,000 increase related to compensation and benefits which was due to the hiring of new staff members, partially offset by a $719,000 decrease in clinical trial expenses. We expect future research and development expenses related to the continued development of CERC-301 and our COMTi platform to increase while development expenses related to the continued development of FP01 are expected to be minimal.

The following table summarizes our research and development expenses for the nine months ended September 30, 2012 and 2013:

	Nine Months Ended September 30,	
	2012	2013
	(in thousands)	
FP01	$ 5,571	$ 3,030
CERC-301	—	1,615
COMTi	—	207
Stock-based compensation	91	125
Other personnel-related costs	882	1,528
Other research and development	175	549
	$ 6,719	$ 7,054

General and Administrative

General and administrative expenses increased by $1.6 million for the nine months ended September 30, 2013 compared to the same period in 2012, primarily as a result of an increase in professional services for legal fees related to new patent filings and compensation and benefits expenses due to hiring of new staff members.

Other Income (Expense)

The decrease in other income (expense) was primarily due to the conversion of our convertible debt into Series A convertible preferred stock on March 30, 2012.

Comparison of Years Ended December 31, 2011 and 2012

Revenue

Revenue decreased from $210,000 in 2011 to $83,000 in 2012. The decrease was attributable to the completion of all work associated with our grant from the NIH.

Research and development expense

Research and development expenses increased by $5.7 million from $2.8 million for 2011 to $8.5 million for 2012. This increase was primarily related to a $3.9 million increase in clinical trial expense related to FP01 and a $1.3 million increase in drug product formulation expense, in each case due to an increased amount of new compositions and methods for FP01 which resulted in two new patents in April and November of 2012. In addition, there was an increase of $927,000 in personnel-related costs associated with increased headcount and a decrease of $615,000 in stock-based compensation.

The following table summarizes our research and development expenses for the years ended December 31, 2011 and 2012:

	Year Ended December 31,	
	2011	2012
	(in thousands)	
FP01	$ 1,523	$ 6,675
Stock-based compensation	744	129
Other personnel-related costs	497	1,424
Other research and development	54	248
	$ 2,818	$ 8,476

General and Administrative Expense

General and administrative expenses increased by $1.3 million for 2012 when compared to 2011, primarily as a result of an increase in business development and market research activities, fees associated with board and committee meetings, and personnel related costs due to hiring of new staff members.

Other Income (Expense)

Other income (expense) changed from other expense of $37,000 during 2011 to other income (expense) of $1,000 during 2012. This change was primarily driven by a decrease in interest expense of $16,000 during 2012 compared to 2011, as interest expense was no longer accrued after March 30, 2012, the date the convertible debt was converted into our Series A convertible preferred stock, and a $22,000 increase in other income as a result of interest income earned on higher cash and cash equivalent balances in 2012 when compared to 2011.

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 $3.5 million and $10.5 million for the years ended December 31, 2011 and 2012, respectively, and $8.0 million and $10.0 million for the nine months ended September 30, 2012 and 2013, respectively. At September 30, 2013, we had an accumulated deficit of $23.9 million, working capital of $4.6 million and cash and cash equivalents of $6.3 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 and convertible debt. Through September 30, 2013, we have received aggregate net proceeds of $26.8 million primarily from the issuance of common and convertible preferred stock and convertible debt. We anticipate funding our operations over the next several years from further sales of debt and equity securities, including this offering.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2011 and 2012 and the nine months ended September 30, 2012 and 2013:

	Year Ended December 31,	
	2011	2012
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (1,845)	$ (9,288)
Investing activities	(62)	(13)
Financing activities	3,018	17,709
Net increase (decrease) in cash and cash equivalents	$ 1,111	$ 8,408

	Nine Months Ended September 30,	
	2012	2013
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (6,538)	$ (9,289)
Investing activities	(8)	(5)
Financing activities	17,709	6,115
Net (decrease) increase in cash and cash equivalents	$ 11,163	$ (3,179)

Net cash (used in) provided by operating activities

Net cash used in operating activities was $9.3 million for the year ended December 31, 2012 and consisted primarily of a net loss of $10.5 million and a $328,000 increase in prepaid expenses resulting from advances paid to a CRO and $83,000 of deferred revenue associated with our grant from the NIH, partially offset by a $988,000 increase in accounts payable and accrued expenses due to increased activities.

Net cash used in operating activities was $1.8 million for the year ended December 31, 2011 and consisted primarily of a net loss of $3.5 million offset by non-cash increases of $1.0 million due primarily to stock-based compensation and an increase in current liabilities associated with the commencement of operating activities of the company.

Net cash used in operating activities was $9.3 million for the nine months ended September 30, 2013 and consisted primarily of a net loss of $10.0 million offset by non-cash increases of $543,000 due mainly to stock-based compensation and a $520,000 increase in accounts payable and accrued expenses due primarily to increased clinical trial activities.

Net cash used in operating activities was $6.5 million for the nine months ended September 30, 2012 and consisted primarily of a net loss of $8.0 million, partially offset by non-cash increases of $398,000 due to stock-based compensation and $1.1 million of increased accounts payable and accrued expenses due primarily to increased business operations.

Net cash used in investing activities

Net cash used in investing activities for the years ended December 31, 2012 and 2011 was $13,000 and $62,000, respectively. Cash used in investing activities primarily consisted of purchases of fixed assets related to purchases of furniture and computer equipment.

Net cash used in investing activities for the nine months ended September 30, 2013 and 2012 was $5,000 and $8,000, respectively. Cash used in investing activities consisted of purchases of furniture and computer equipment.

Net cash provided by financing activities

Net cash provided by financing activities was $17.7 million for the year ended December 31, 2012, which was primarily due to net proceeds received from the sale and issuance of our Series A convertible preferred stock and warrants.

Net cash provided by financing activities was $3.0 million for the year ended December 31, 2011, which was primarily due to $3.0 million in proceeds from the convertible debt issued.

Net cash provided by financing activities was $6.1 million for the nine months ended September 30, 2013, which was primarily due to net proceeds received from the sale and issuance of our Series A-1 convertible preferred stock and warrants.

Net cash provided by financing activities was $17.7 million for the nine months ended September 30, 2012, which was primarily due to net proceeds received from the sale and issuance of our Series A convertible preferred stock and warrants.

Operating and Capital Expenditure Requirements

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

We believe that our existing capital resources, together with the net proceeds from this offering, will be sufficient to fund our operations through at least . However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we raise additional funds through collaboration and licensing agreements with third parties, it may be necessary to relinquish valuable rights to our product candidates, technologies or future revenue streams or to grant licenses on

terms that may not be favorable to us. Our future capital requirements will depend on many forward-looking factors, including:

- the progress and results of the Phase 2 clinical program for CERC-301 and changes to our development plan with respect to CERC-301, if any;
- our plan and ability to enter into collaborative agreements for the development and commercialization of our product candidates;
- the number and development requirements of any other product candidates that we pursue;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs, timing and outcome of regulatory review of our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for any of our product candidates for which we receive marketing approval;
- the costs and timing of any product candidate acquisition or in-licensing opportunities;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and in territories outside the United States; and
- the timing and success of this offering.

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

Contractual Obligations and Commitments

The following is a summary of our long-term contractual cash obligations as of December 31, 2012 (in thousands):

	Total	Less than One Year	1-3 Years	3-5 Years	More than 5 Years
Contractual Obligations(1)	—	—	—	—	—
Operating lease obligations	$ 80	$ 80	$ —	$ —	$ —
Total contractual obligations	$ 80	$ 80	$ —	$ —	$ —

(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) Operating lease obligations reflect our obligation to make payments in connection with the lease for our office space which we vacated in October 2013.

(3) Operating lease obligations do not reflect our obligations pursuant to the terms of a lease agreement entered into on August 8, 2013 for our new office space located in Baltimore, Maryland.

Pursuant to the terms of such lease, our aggregate cash obligation is $712,000 broken down as follows: (i) through the end of the 2013 fiscal year is $107,000, (ii) for one to three years is $448,000, (iii) for three to five years is $157,000 and (iv) for more than five years is $0.

Off-Balance Sheet Arrangements

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

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. We had cash and cash equivalents of $9.5 million as of December 31, 2012 and $6.3 million as of September 30, 2013, consisting of cash and money market funds. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. We do not believe an immediate 10% increase in interest rates would have a material effect on the fair market value of our cash and money market funds, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

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

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company committed to becoming a leader in the development and commercialization of innovative drugs that address the needs of underserved patients with nervous system disorders. Members of our management team and board of directors have previously played key roles in the development or commercialization of successful pharmaceutical products, including the blockbuster neuroscience products Prozac, Zyprexa, Lyrica, Cymbalta and Neurontin. Leveraging our knowledge of the nervous system and clinical development experience, we have identified and in-licensed a portfolio of clinical and preclinical compounds that we believe are best-in-class and where human proof of concept has been established for the compound or the target. We received fast track designation in November 2013 for our lead clinical product candidate, CERC-301, which is currently in Phase 2 development as an oral, once-a-day, adjunctive antidepressant. We believe CERC-301 will be a first-in-class medication that will cause a significant reduction in depression symptoms in a matter of days, as compared to weeks or months with conventional therapies. We are also developing product candidates from a proprietary platform of compounds specifically engineered to inhibit catechol-O-methyltransferase, or COMT, which we refer to as our COMTi platform. These product candidates are potentially best-in-class and have a mechanism of action with demonstrated human proof of concept in subjects with schizophrenia, Parkinson's disease and various impulse control disorders. We believe our management team's experience enables us to develop and utilize cutting-edge drug development methodologies designed to increase the probability of clinical success by reducing placebo response rates and enhancing efficacy signals in our clinical trials for our product candidates. We believe these methodologies may also accelerate time to market and reduce overall development costs.

Most approved depression therapies are characterized by a delayed onset of therapeutic benefit, high rates of treatment failures and low rates of remission, leaving patients without relief for weeks to months, if at all. They are also characterized by a number of significant side effects, including gastrointestinal disturbance, dizziness, drowsiness, insomnia and sexual dysfunction, which greatly reduce compliance. CERC-301 belongs to a class of compounds known as antagonists, or inhibitors, of the N-methyl-D-aspartate, or NMDA, receptor, a receptor subtype of the glutamate neurotransmitter system that is responsible for controlling neurological adaptation. Multiple recent controlled clinical studies have provided evidence that NMDA receptor antagonists can have significant antidepressant activity within several days of administration. Efficacy of the class is further supported by the common off-label use of ketamine throughout the United States as a rapid-acting antidepressant, or RAAD, in bipolar depression and MDD. Ketamine is an anesthetic that is a non-selective NMDA receptor antagonist, is not registered for use as an antidepressant and has several significant limitations, including the need for repeated intravenous administration in a clinic and undesirable side effects such as increases in blood pressure and significant psychotomimetic effects, including intoxication and hallucinations. CERC-301 has potential competitive advantages over current treatments because it is orally administered and it selectively blocks the NMDA receptor subunit 2b, or NR2b, which we believe provides rapid and significant antidepressant activity without many of the adverse side effects of ketamine and other non-selective NMDA receptor antagonists. In October 2012, the National Institute of Mental Health, or NIMH, published the results of a human proof of concept study of CERC-301 in five subjects with treatment resistant depression, or TRD, which demonstrated a rapid onset of antidepressant effect based upon two secondary endpoint depression assessment scales. We licensed CERC-301 from Merck & Co., Inc. and its affiliates, or Merck.

We have begun enrollment in a 135-subject Phase 2 double-blind, placebo-controlled trial in subjects suffering from major depressive disorder, or MDD, who, despite their current treatment with selective serotonin reuptake inhibitors, or SSRIs, or serotonin-norepinephrine reuptake inhibitors, or SNRIs, are experiencing a severe depressive episode with recent active suicidal ideation. While suicidal ideation is recognized as a significant risk in depression, it represents a substantial unmet need as most

antidepressant studies exclude subjects with active suicidal ideation and thus do not address the treatment of these subjects. We are administering CERC-301 once a day as an adjunctive, or add-on, treatment to subjects' current medications. We are measuring the onset and maintenance of antidepressant effects. The primary endpoint is antidepressant effect at seven days as measured by the Hamilton Depression Inventory 17 item scale, or HAMD-17, which is a scale that has been used to measure antidepressant effect in drug registration trials. A key secondary endpoint is the HAMD-17 measurement of maintenance of antidepressant effect at 28 days and an exploratory endpoint is the Beck Scale for Suicidal Ideation, or BSSI, a questionnaire that is used to detect and measure the severity of suicidal ideation, at each subject visit. If we achieve the primary endpoint, we intend to present the study results to the United States Food and Drug Administration, or FDA, as evidence of an adequately powered, well-controlled study and plan to apply for breakthrough therapy designation for CERC-301 with the FDA. We anticipate study completion and receipt of complete data from this trial by year-end 2014. We believe that even achieving antidepressant effect at 28 days will provide significant value and may constitute a basis for marketing approval.

We believe that CERC-301 also has the potential to be useful as an agent to treat acute suicidality and as monotherapy in MDD, bipolar depression and other neuropsychiatric conditions. As such, we are preparing to initiate an inpatient Phase 2 study of CERC-301 in the first half of 2014, in both severely depressed subjects experiencing active suicidality and in healthy volunteers. The study will examine safety and efficacy biomarkers across a broad range of doses and in different subject populations. Clinical measures such as reduction of suicidality and improvement of mood will also be evaluated. We anticipate study completion and receipt of complete data from this trial by year-end 2014. These results will guide future studies for other dosing regimens and other indications, such as the treatment of acute suicidality.

In addition to CERC-301, our ongoing and collaborative relationship with Merck has resulted in our in-licensing of exclusive, worldwide rights to inhibitors of COMT. COMT is an enzyme that causes the degradation of dopamine in the brain and its inhibition has demonstrated applicability in treating subjects with neuropsychiatric conditions, including schizophrenia, Parkinson's disease and various impulse control disorders. The COMTi platform includes access to a library of approximately 2,000 compounds specifically engineered to increase dopamine levels in the prefrontal cortex, which is the region of the brain that is responsible for verbal learning, working memory, attention tasks and decision making, all of which are unique human attributes that we collectively refer to as executive function. Moreover, our development efforts are specifically focused on a new generation of potent inhibitors that avoid off-target toxicity and side effects, such as liver toxicity and diarrhea, which are often seen with the previous generation of inhibitors, such as tolcapone and entacapone. In 2014, we intend to select lead candidates from the COMTi platform and to initiate two programs for the treatment of various cognition-related disorders.

Members of our management team have extensive pharmaceutical product development and commercialization experience and they have played key roles in the development or commercialization of Prozac, Zyprexa, Lyrica, Cymbalta and Neurontin, each of which is a neuroscience product that has generated over $1.0 billion of annual revenues. Collectively, our directors and officers have contributed to the submission of numerous Investigational New Drug Applications, or INDs, and nine New Drug Applications, or NDAs, to the FDA. The Chairman of our Board, Sol Barer, Ph.D., was previously the Chairman and CEO of Celgene Corporation. Leveraging the experience of our management team, we obtained IND clearance and received fast track designation for CERC-301 from the FDA, initiated a Phase 2 clinical trial of CERC-301 and initiated lead candidate selection activities for the COMTi platform, all within eight months of securing licenses to CERC-301 and the COMTi platform.

Our Strategy

Our goal is to be a leader in the development and commercialization of innovative drugs that address human nervous system disorders. We systematically identify platforms and product candidates for which human proof of concept exists in the intended indication, for either the target or the compound, and for which biomarkers are available to measure therapeutic response. We target conditions where current treatments fail to address medical needs, and where we can apply clinical strategies to maximize efficacy signal to noise ratios. These approaches include using personalized therapeutics and advanced placebo mitigation techniques to facilitate marketing approval and commercialization success for our product candidates.

Our strategic objectives include:

- ***Rapidly Advance the Clinical Development of CERC-301.*** We are developing CERC-301 as an oral, once-a-day adjunctive medication for people who are failing to respond to their current antidepressant treatment, are severely depressed and have recently experienced active suicidal ideation. In addition to a Phase 2 clinical trial for CERC-301 as an adjunctive therapy, we are preparing to initiate an inpatient Phase 2 study of CERC-301 in both severely depressed subjects experiencing active suicidality and in healthy volunteers. We expect complete data from both of these studies by year-end 2014. If we see substantive evidence of a therapeutic effect from either of these two studies, we plan to meet with the FDA to discuss applying for breakthrough therapy designation and pursuing an expedited development program. Similarly, if we demonstrate safety and efficacy in these Phase 2 studies, we will consider also initiating separate development programs in other indications, such as acute suicidality and as monotherapy in MDD and other neuropsychiatric conditions.

- ***Use our COMTi Platform to Build a Pipeline of Product Candidates for Disease States Where Impaired Executive Function is a Core Symptom.*** By targeting COMT inhibition, for which human proof of concept in multiple conditions exists for the COMT inhibition class of drugs, we have the ability to address the impairment of executive function in a highly specific manner, guided by biomarkers and pharmacogenomics. Our COMTi platform, which we licensed from Merck, provides exclusive access to a library of approximately 2,000 compounds that inhibit COMT. In 2014, we intend to select lead candidates from the library and to initiate two programs for treatment of various cognition-related disorders. In addition to compounds that we may develop on our own, we are exploring early development collaborations with third parties on an indication-specific basis in order to maximize value of our COMTi platform.

- ***Establish Specialty Segment Commercialization and Marketing Capabilities in the United States.*** We intend to selectively retain commercialization rights for certain of our product candidates and to build specialty commercialization capabilities in the United States, which we may complement with co-promotion agreements with partners. We also plan to seek to commercialize any approved products outside the United States.

- ***Establish Collaborations to Maximize Value.*** Collaborations may provide access to the considerable scientific, development, regulatory and commercial capabilities of biopharmaceutical corporations, potentially providing us with additional infrastructure to more efficiently develop and commercialize assets in our product candidate portfolio. Our selection criteria for potential partners include market presence in complementary areas and an ability to contribute to the creation of the highest quality data sets and registration materials for submission to United States and/or foreign regulatory authorities when we seek marketing approval for our product candidates.

- ***Expand our Product Candidate Portfolio Through Strategic Acquisitions.*** In migrating away from the centralized research and development model of the past, many major pharmaceutical

companies have deemphasized their neuroscience discovery and development programs in recent years. Given our focus and expertise, these programs may represent compelling acquisition opportunities. We believe we have the ability to identify, evaluate and procure valuable product programs that are consistent with our commitment to develop drugs that address the needs of underserved patients with nervous system disorders. We plan to continue to leverage these opportunities to expand our product candidate portfolio in a fashion that fits within our core strategy and enhances our overall value.

Product Pipeline

The following table summarizes key information about our three product candidates and/or platforms:

Product Candidate / Platform	Indication	Stage of Development	Anticipated Milestones / Study Summary
CERC-301	MDD adjunctive antidepressant with rapid onset	Phase 2	• Results by year-end 2014. • Onset at seven days, maintenance at 28 days.
	Acute suicidality	Phase 2	• Results by year-end 2014. • Inpatient dose ranging in subjects experiencing active suicidality and in healthy volunteers.
COMTi Platform	Conditions with Cognitive Impairment	Preclinical	• Lead candidate selection in 2014. • File INDs late 2015 and 2016. • Begin clinical development with first-in-man study.
FP01	Chronic Persistent Cough	Phase 2	Collaborative partnership to continue Phase 2 trial

CERC-301

Current Depression Treatment Paradigm and Limitations

Depression is one of the most common serious medical and psychiatric disorders, with greater than 150 million adults worldwide suffering from MDD at any given time, according to a 2003 report by the World Health Organization, or WHO, titled *Investing In Mental Health*. According to the NIMH, approximately 20 million adults in the United States, which represents approximately 9.5% of its entire adult population, will suffer from a depressive illness in their lifetimes. Furthermore, suicide is a grave complication associated with depression. Studies have shown that approximately 60% to 80% of severely depressed patients have experienced suicidal ideation. Over the past 50 years, almost all depression

therapies have 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 approximately three to six weeks to take effect, and patients frequently 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. Currently, physicians are relegated to switching to other monoamine antidepressants, and patients will frequently undergo two or three courses of treatment, each lasting several months, before achieving satisfactory relief. The depression frequently persists and additional medications may need to be used adjunctively. These adjunctive agents include atypical antipsychotics, like aripirazole and quetiapine, or other agents such as buproprion and lithium. While certain patients experience improvement in their depressive symptoms when these additional therapies are added to their existing treatments, according to the STAR-D Report, approximately 38% of patients who suffer from depression failed to respond even with the addition of currently available add-on therapies.

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.

We believe that most of the 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 three to six weeks before patients experience the onset of the drugs' therapeutic effect; full effect is frequently not seen until 12 weeks.

- ***High rates of treatment failures and low rates of remission.*** Even with the widespread availability of SSRIs and SNRIs, MDD remains a leading cause of disability in the world. In 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 and insulin resistance.

Emergence of NMDA Receptor Antagonists as Antidepressants

Recent research on RAADs is reshaping expectations regarding what might be achieved through antidepressant treatment. Multiple controlled clinical studies have provided evidence that agents blocking NMDA receptor function can cause significant antidepressant mood effects within 24 hours of administration. Clinical use of, and research with, ketamine has unveiled new insights into the neurobiology of depression and points to new and otherwise unexpected classes of antidepressant medications such as NR2b antagonists. Based on the results of multiple studies it has been demonstrated that when the NMDA receptor system is inhibited, significant clinical improvement in

depression symptoms may occur within hours to days of drug administration. These agents, which work on the glutamate system by blocking NMDA receptors, have the potential to work quickly with improved response and remission and lack compliance-limiting adverse side effects such as sexual dysfunction. 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.

Ketamine, which is increasingly being used off label to achieve rapid relief in depression patients, has been the subject of multiple clinical studies, which have demonstrated treatment success in treating MDD, treatment resistant depression, or TRD, and bipolar depression. Moreover, studies have also demonstrated that ketamine, in contrast to conventional antidepressants that may actually worsen suicidal ideation, causes a rapid reduction in suicidal ideation. However, non-selective NMDA antagonists such as ketamine have significant limitations, including a propensity to cause significant psychotomimetic effects such as intoxication and hallucinations, as well as increases in blood pressure. In addition, psychiatric use of ketamine is limited by the need for intravenous administration, the unapproved nature of the treatment, the need for repeated infusions and the unknown safety profile of multiple infusions administered sub-chronically to humans. In addition, ketamine is a Schedule III drug and is prone to abuse.

Our Solution

We are developing CERC-301 as a first-in-class, oral, once-a-day adjunctive medication for patients who are severely depressed, have recently experienced active suicidal ideation, and are experiencing an inadequate response to their antidepressant treatment. CERC-301 is a therapeutic agent that inhibits glutamate-driven NMDA receptors within the nervous system by selectively blocking the NR2b subunit of the NMDA receptor. We believe that this selectivity in inhibition will provide both the rapid antidepressant and suicidality reduction effects of non-selective NMDA antagonists, without many of their side effects. 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. Additionally, in October 2012, the NIMH published the results of a study of CERC-301 in five TRD subjects, which we refer to as the 2012 NIMH Study, which demonstrated a rapid onset of antidepressant effect of CERC-301 in TRD subjects based upon two of the study's secondary efficacy endpoint depression scales without the side effects commonly seen with non-selective NMDA receptor antagonists.

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

- convenient, once-a-day oral dosing;
- minimal psychotomimetic effects; and
- ability to use continuously for the prevention of relapse.

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

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

Our Program

Current Development Plan

We are developing CERC-301 as an adjunctive treatment with a rapid onset of action and expect to improve upon the efficacy of existing therapies. Furthermore, we believe CERC-301 will be well tolerated and will seek to minimize many of the side effects of the leading adjunctive treatments, such as atypical antipsychotics, whose treatment efficacy is hindered by side effects such as weight gain and insulin resistance. We expect that a drug with these attributes will lead to improved compliance and outcomes. We believe an antidepressant with rapid onset of effect can possibly provide its greatest benefit by quickly relieving suicidality, a risk factor for suicide. Studies have shown that approximately 60% to 80% of severely depressed patients have experienced suicidal ideation. In our two Phase 2 studies we are exploring the ability of CERC-301 to rapidly reduce suicidal ideation. This feature has the potential to address a growing problem and become a key differentiator from existing and pipeline antidepressants.

Study Clin301-201: Placebo-Controlled, Sequential Parallel Study of CERC-301 in the Adjunctive Treatment of MDD

Clin301-201 is a double-blind, placebo-controlled trial in 135 MDD subjects who, despite their current treatment with SSRI and SNRI therapies, are severely depressed and have recently experienced active suicidal ideation. We are administering CERC-301 once a day as a therapy adjunctive to subjects' current medications. This study examines the 8 mg dose of CERC-301, the dose that demonstrated antidepressant effects in the 2012 NIMH Study and that we believe to be safe. We are measuring tolerability and the onset and maintenance of antidepressant effects of 8 mg daily dosing and have begun enrollment. The primary endpoint is antidepressant effect at seven days as measured by the HAMD-17. A key secondary endpoint is maintenance of antidepressant effect at 28 days measured with the HAMD-17 and an exploratory endpoint is the measurement of suicidality throughout the study with the BSSI, at each subject visit. We believe that achieving antidepressant effect at 28 days — our key secondary endpoint — will provide significant value and may constitute a basis for marketing approval. If we achieve the primary endpoint, we plan to apply for breakthrough therapy designation for CERC-301 and we intend to propose to the FDA that this study be deemed an adequately powered, well-controlled trial for purposes of our future NDA submission. We anticipate study completion and receipt of complete data by year-end 2014.

Enrollment Strategy: We are enrolling subjects that are severely depressed and have recently experienced active suicidal ideation while undergoing treatment with an SSRI or SNRI. While the primary goal of Clin301-201 is to show robust antidepressant effects at seven days with a secondary goal of 28 days, by enriching the subject population with subjects who have recently experienced active suicidal ideation, we will explore whether once-a-day 8 mg dosing with CERC-301 can successfully suppress suicidality compared to placebo. While suicidal ideation is recognized as a significant risk in depression, most antidepressant studies exclude subjects with active suicidal ideation and thus do not address the treatment of these patients. We believe this population represents the subsegment of depressed patients with the greatest unmet need and thus may be easier to enroll and have less placebo response. Moreover, we believe that studying this subject population may increase the probability that we receive breakthrough therapy designation from the FDA, if our study results are positive.

Adjunctive Therapy: CERC-301 will be administered once a day as an adjunctive therapy along with each subject's current antidepressant treatment in subjects who are failing to respond to their current therapy. We believe pursuing approval as an adjunctive treatment enhances our ability to achieve appropriate levels of pricing, formulary access and reimbursement.

Study Design: We believe the greatest barrier to successful trials in depression is a high placebo response rate, which obscures the true effect of the treatment. While there are various potential sources of this placebo effect, the inclusion of inappropriate subjects and variability of endpoint assessments

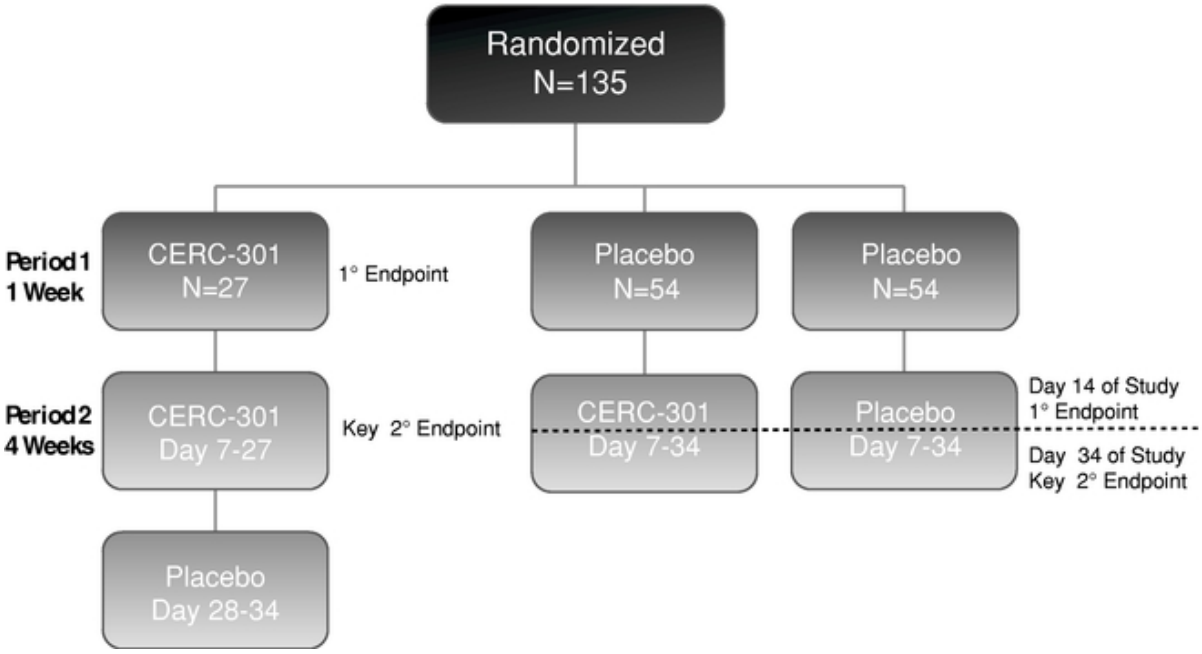
contribute very significantly to this problem. We are combining the following methods to mitigate those effects, thus maximizing our chances of clinical success in the trial:

- **Independent Blinded Central Rating:** Trials in depression are particularly vulnerable to placebo effects because it is difficult to assess mood, both quantitatively and objectively. Further, a subject's mood can improve just from interaction with medical professionals during a trial. In our Phase 2 study, we are centrally evaluating the subjects for the appropriateness of their inclusion and the measures of their depression scales are performed by blinded, remote and centralized raters. These central raters interview the subjects by telephone prior to enrollment to ensure correct diagnosis and assessment of disease severity. We believe this approach minimizes the bias that is associated with the understandable desire of subjects to enroll in, and the desire of the investigators to enroll subjects in, the clinical trial. In addition, the centralized raters will collect the primary endpoint data, measured using the HAMD-17 rating scale. We believe that using this centralized evaluation method will provide a more accurate measure of drug response and a lower likelihood of subjects showing a spurious improvement.

- **Sequential Parallel Comparison Design:** We are using the innovative sequential parallel comparison design, or SPCD, developed by Dr. Maurizio Fava, a professor at Harvard Medical School, to help minimize placebo response which has been shown in numerous studies to yield a more accurate measure of drug response. This approach improves signal detection compared to simple parallel studies. Phase 2 depression studies using the SPCD have demonstrated this minimized placebo response rate. For example, Alkermes plc is using this design concept in its registration program of ALKS-5461, an antidepressant. The SPCD uses a two-stage process to weed out subjects on placebo who show at least a 50% improvement, or placebo response. Based on historical trials, about one-third of subjects are expected to have a placebo response. The first stage of subject randomization includes a large cohort that receives placebo and a smaller number of subjects who receive the product candidate. This establishes which subjects respond to a placebo, leaving only placebo non-responders to be analyzed in the second stage. In the second stage, subjects who did not respond to placebo are re-randomized to receive either the compound or placebo. Subjects who receive the compound in stage one receive placebo in stage two. Placebo responders from stage one also receive placebo in stage two to preserve the integrity of the trial, keeping subjects and physicians blinded. However, those data are not used in the final statistical analysis.

Although data are analyzed for each stage separately, the global results for both primary and secondary endpoint analyses are calculated by combining the statistics for the two stages with equal weighting. Even though the data from stage one are complicated by the same biases as in conventional trials, combining the data from the two stages in SPCD provides a statistical advantage because the larger overall sample size increases the power. The use of SPCD's in other studies has led to a substantial reduction in the number of subjects required for a study compared to that required for conventional depression trials. We believe the SPCD will enhance our ability to detect treatment effects in our Clin301-201 study.

The following diagram shows the SPCD of our Clin301-201 study:



- **Use of Biomarkers:** Biomarkers are measured characteristics which may be used as an objective indicator of drug response and, as such, their use has the potential to facilitate drug development. Plasma brain derived neurotropic factor, or BDNF, is a commonly accepted biomarker of antidepressant effect. BDNF is a member of the neurotrophin family and plays a critical role in the survival, differentiation and outgrowth of peripheral and central neurons during development and in adulthood. In a 2012 paper titled *Plasma Brain-Derived Neurotrophic Factor Levels Predict the Clinical Outcome of Depression Treatment in a Naturalistic Study*, it was shown that blood levels of BDNF are decreased in subjects suffering from MDD, correlate with the severity of depression and rise in response to antidepressant treatment. A 2012 paper titled *Brain-Derived Neurotrophic Factor Val66Met Polymorphism and Antidepressant Efficacy of Ketamine in Depressed Patients* suggests that increased BDNF function is a necessary component of the antidepressant effects of ketamine and other NMDA antagonists. For example, in the 2012 NIMH Study, BDNF increased significantly in the CERC-301 treatment arm. Recent reports in humans have suggested that an individual's genetic version, or allele, of BDNF is predictive of antidepressant response to NMDA antagonists. In the 2012 NIMH Study, BDNF increased 75% in the CERC-301 treatment arm. We are evaluating BDNF and its alleles in the Clin301-201 study in order to guide future studies.

Clin301-200: Pharmacodynamic Dose Finding Study

At a meeting with the FDA in July 2013, the FDA recommended that we undertake a study of CERC-301 as a monotherapy for depression and an outpatient dose ranging study. In advance of conducting these studies, we will conduct Clin301-200 to examine CERC-301's biological effect to optimize dose regimens and to explore its utility in other indications. Clin301-200 will be an inpatient Phase 2 study, in both suicidal patients and in healthy volunteers. We plan to include various efficacy and safety biomarkers across a broad range of dosing regimens. Assuming our protocol is acceptable to the FDA, we anticipate study completion and receipt of complete data from this trial by year-end 2014. Based on these trial results, combined with our Clin301-201 study, we will evaluate CERC-301's other potential commercial applications, such as monotherapy in MDD and other neuropsychiatric disorders and the treatment of acute suicidality.

In Clin301-200, we intend to examine a wide range of doses of CERC-301 during daily oral dosing for seven days in up to nine cohorts of healthy volunteers, elderly volunteers and subjects with severe depression and active suicidal ideation. This study, which we expect will include approximately 70 subjects, will use pharmacokinetic and pharmacodynamic measures, including continuous blood pressure measurement, that will help us choose doses to be studied in the trials recommended by the FDA. We will quantitatively describe the effects of CERC-301 on suicidality and on biomarkers, including plasma BDNF, which can be viewed as markers of drug effect and, potentially, predictors of antidepressant response.

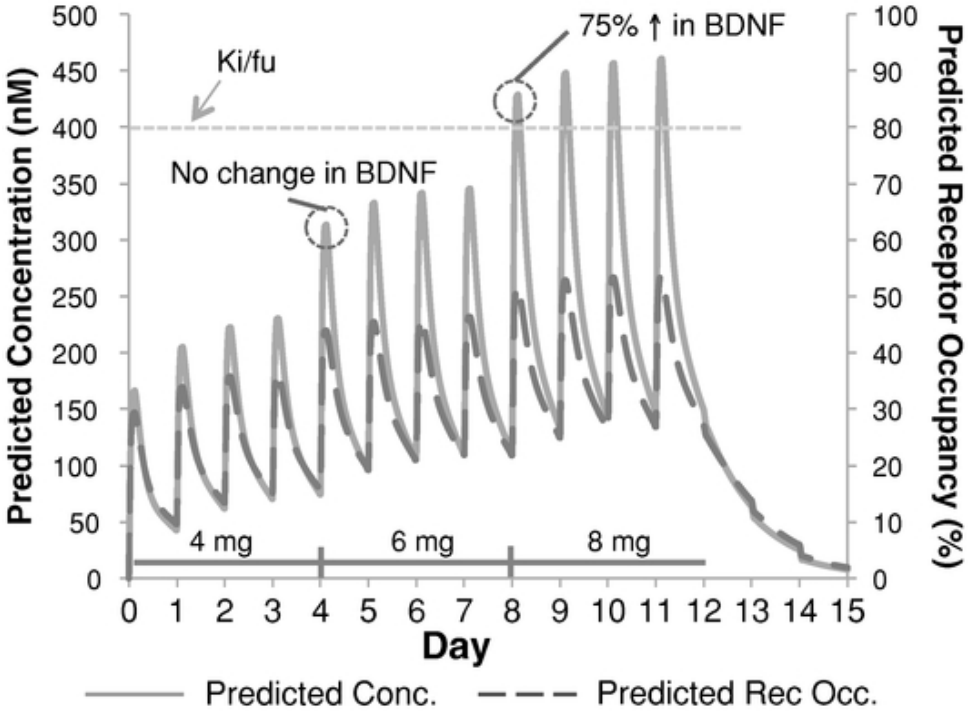
Clin301-200 will first examine a full range of potential doses in a healthy volunteer cohort with equal numbers of each gender to better understand the relationship among dose, plasma concentrations and the emergence of adverse events at higher doses. We plan to use pharmacodynamic signals such as recording electrical activity along the scalp, or EEG, and recording the biophysiological changes that occur during sleep, or polysomnography, to map these relationships to brain effects and receptor occupancy. We will then examine a cohort of elderly volunteers to provide information regarding the effects of age on these relationships. Clin301-200 will lastly examine a cohort of depressed subjects with active suicidal ideation to explore the relationship of these biophysiological measures to the clinical effects of CERC-301. We plan to use the results of this study to provide the information needed for subsequent studies to evaluate the safety and efficacy of doses above or below the 8 mg dose currently being studied in our Clin301-201 study.

Summary of Prior Clinical and Preclinical Studies

Human Proof of Concept Study in Treatment Resistant Depression

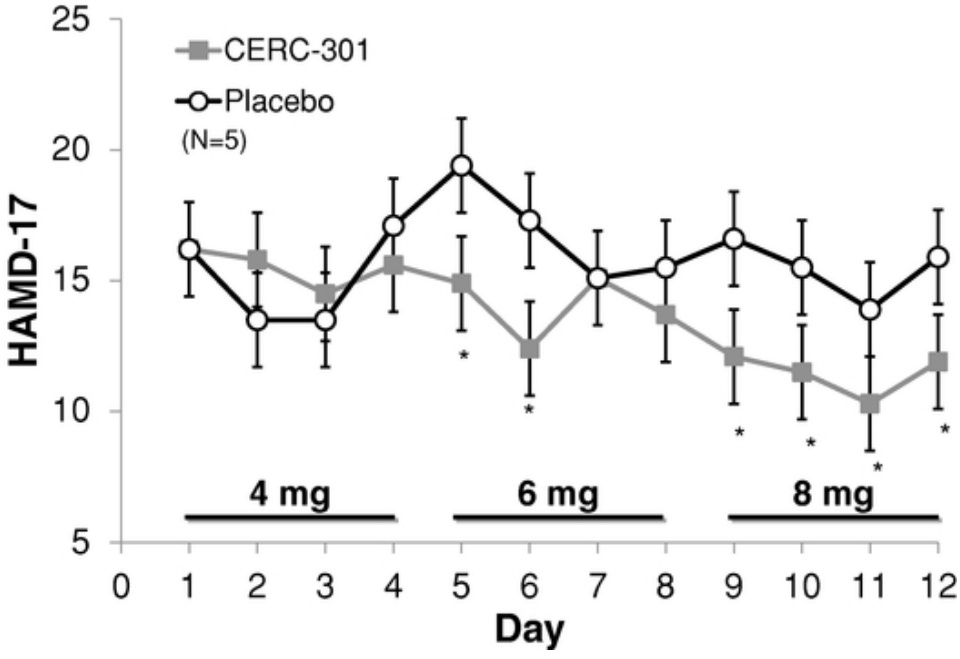
The 2012 NIMH Study was a single center, randomized, double-blind, placebo-controlled crossover study of five subjects with TRD to evaluate the potential antidepressant efficacy and tolerability of CERC-301. It was conducted at the Mood and Anxiety Disorders Program of the NIMH Research Campus, where subjects were hospitalized for the duration of the study. Male and female subjects of the NIMH, aged 18 to 55 years, were recruited to participate; all subjects were diagnosed with MDD and were currently depressed without psychotic features. Subjects were required to have a score of 22 or higher on the Montgomery-Asberg Depression Rating Scale, or MADRS, at screening and at baseline, the day of first dose of study medication. In addition, subjects had to have previously failed at least two adequate antidepressant trials in the current depressive episode. Exclusion criteria included a recent history of drug abuse, diagnosis of bipolar disorder, psychotic features, suicidal ideation, serious unstable medical disorder or condition, previous use of ketamine or phencyclidine, and concomitant treatment with psychotomimetic medications in the two weeks before the study or electroconvulsive therapy in the three months before the study.

Following a one week drug-free period, five subjects were randomized in a double-blind manner to receive either CERC-301 or placebo for 12 days. Initial doses were 4 mg/day of CERC-301 for four days, then escalated to 6 mg/day for four days and then 8 mg/day for four days. The study's medication dose was increased in a blinded fashion every four days until completion of the treatment. At day 12, the study drug was discontinued; subjects remained drug-free for 14 days and then crossed over to the other treatment condition. Dosage in the second experimental treatment condition (days 27 through 38) was identical to the first crossover phase. By day nine, plasma BDNF levels were significantly higher in patients receiving CERC-301 than in those receiving placebo ($p = 0.03$). This corresponded to the achievement of 50% receptor occupancy, predicted, in the first day of 8 mg dosing, as demonstrated in the accompanying graphic.



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

Treatment effect emerged after 6mg daily dose and was sustained at 8mg



Phase 1 Studies

In 2004 through 2005, three Phase 1 clinical trials of CERC-301 in a total of 60 healthy volunteers were completed by Merck, each of which measured the safety and assessed the pharmacokinetics, or PK, of CERC-301. The first study, Study 001, measured single doses of the drug in a healthy, fasted and young male population. The second study, Study 002, measured multiple doses in a healthy, fed and young male population. The final study, Study 003, measured single doses in healthy elderly male and female populations. CERC-301 was generally well tolerated, with the exception of dose-related increases in blood pressure and central nervous system related adverse effects, all of which were transient and mild to moderate in severity. No serious adverse effects were experienced. There were no psychotomimetic effects in those subjects given less than 20 mg while fasting, which is five times the exposure, or amount of drug in the bloodstream, that we believe is needed to have antidepressant effects. Further, no clinically significant abnormalities were noted in respiratory rate, heart rate, routine blood and urine chemistry panels, electrocardiogram tests, or physical examinations, including neurologic examinations. CERC-301 demonstrated an acceptable safety profile in the fed state at 8 mg dose in these PK studies. In the 2012 NIMH Study, where CERC-301 was administered on an increasing basis to 8 mg daily in the fed state, no elevations in blood pressure, dissociative adverse effects or serious adverse effects were observed.

Two additional Phase 1B studies were completed in subjects with moderate Parkinson's disease, for a total of 38 subjects, which did not show efficacy to control movement disorders. However, contrary to what was observed in the elderly pharmacokinetic Study 003, both studies, at single doses of 7 mg in the fed state, showed no meaningful blood pressure elevations compared to placebo. Therefore, we believe that at an 8 mg daily dose in fed state, which is the dose selected for our ongoing Phase 2 study in MDD subjects, CERC-301 will be safe and well tolerated.

Preclinical Studies

Completed preclinical studies of CERC-301 include the evaluation of safety pharmacology, pharmacokinetics and toxicology of CERC-301 in conscious animals, all of which have demonstrated a safety profile sufficient to enable ongoing and planned human clinical studies. The engagement of CERC-301 with brain NR2b, or target engagement, has also been demonstrated in rats, dogs, monkeys and in human cadaver tissue. The predicted blood exposure required to achieve target engagement has been described in these species, and this exposure is achieved with 8 mg daily administration in humans. Live animal model studies have provided promising support for CERC-301's efficacy in treating Parkinson's disease related movement disorders, chronic pain and depression. Additional preclinical studies are ongoing.

COMTi Platform

Overview

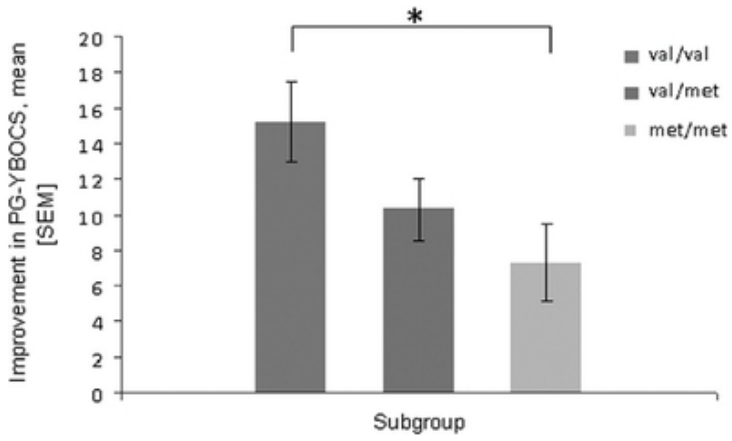
In March 2013, we acquired rights to our COMTi platform by means of an exclusive, worldwide license from Merck. In 2014, we intend to select lead candidates and to initiate two programs for treatment of various disorders associated with cognitive impairment. These programs target the prefrontal cortex dopamine system to specifically improve working memory and executive function, which are key components of cognition.

The neurotransmitter systems that are involved in cognitive decline are targets for drug development, and include acetylcholine, serotonin, dopamine, glutamate and histamine. Most of these targets for drug development have a wide ranging impact on different brain functions, and, as such, most drug development efforts are fraught with the lack of specificity of clinical effect of the drugs tested. On the other hand, impairment of working memory, attention, verbal learning and decision making or executive function, are governed specifically by dopamine in the prefrontal cortex, or PFC. COMT is an enzyme that breaks down dopamine and is key to the fine tuning of dopamine in the PFC.

As a result of these characteristics, we believe COMT inhibition is a preferred target for treatment of cognitive impairment in many conditions where loss of executive function is a key symptom. Specifically, COMT inhibition has been shown to significantly improve cognitive functioning in persons suffering from schizophrenia, Parkinson's disease and various impulse control disorders.

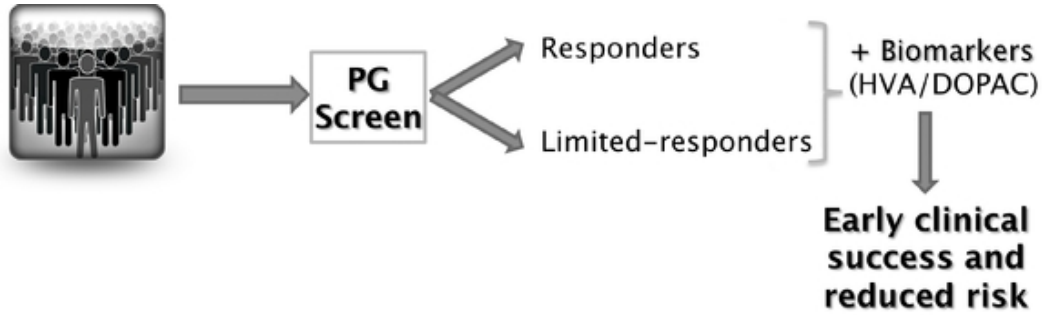
Entacapone and tolcapone are two commercially available COMT inhibitors used to treat movement disorder in Parkinson's disease. Both drugs are designed to inhibit COMT outside of the nervous system and are administered with levodopa (the precursor to the neurotransmitter dopamine), from three to 10 times a day. Pilot studies utilizing tolcapone have repeatedly demonstrated an improvement in executive function in normal volunteers and in patients with various conditions that are associated with cognitive impairment. These changes were associated with functional improvements of the underlying conditions. Despite its efficacy, tolcapone use is hampered by side effects including diarrhea and liver toxicity. Entacapone does not penetrate the brain while tolcapone only does so modestly. Because of these factors, neither drug is used clinically to enhance executive function.

Our COMTi platform consists of compounds specifically engineered to penetrate the nervous system and to preferentially inhibit brain COMT. In addition, COMT inhibition has two attributes that enable drug development — genetic variability and the availability of biomarkers. A genetic variation in the COMT enzyme, the Val allele, enhances the enzyme's baseline level activity and is linked to reduced executive function in normal volunteers and in other disorders associated with cognitive impairment including, schizophrenia, Parkinson's disease and various impulse control disorders. The Val:Val allele, which is one of three possible alleles, is present in 40% of the North American population, as stated in a 1999 epidemiology paper titled *Global Variation in the Frequencies of Functionally Different Catechol-o-Methyltransferase Alleles*. In a series of hypotheses-driven studies, it has been repeatedly demonstrated that the Val allele is linked to reduced working memory/executive function and functional MRI-assessed PFC physiological efficiency, and increased response to tolcapone. These results suggest that COMT inhibition may improve PFC executive function in a genotype-specific and more predictable manner. This represents an opportunity to ameliorate symptoms in patients with various diseases associated with frontal cortex dysfunction who carry this genetic subtype. Support of this stratification of subjects by genotype, or pharmacogenomic approach, is found in a 2013 article titled *A Proof of Concept Study of Tolcapone for Pathological Gambling: Relationships with COMT Genotype and Brain Activation*, which demonstrated that the this genotype is predictive of response to brain COMT inhibition. As indicated in the figure below, in this study of pathological gambling, the Val:Val subjects had a significantly improved response when compared to the other subject genotypes. By targeting this genotype, we believe we could see a significant improvement in magnitude and reliability of drug response.



Tolcapone-induced improvement in Yale-Brown Obsessive Compulsive Scale, modified for Pathological Gambling (PG-YBOCS); correlated w/ BOLD fMRI

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



Our COMTi Platform

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

Development Plan

In 2014, we intend to select lead candidates and to initiate two programs for the treatment of various cognition-related disorders. We are undertaking preclinical chemistry, drug metabolism, PK, pharmacodynamics, or PD, and safety studies to aid in lead candidate selection. Initial chemistry efforts will test potential lead candidates in in vitro and in vivo studies to further investigate PK characteristics and PD effects. Based on these initial assessments, a short list of compounds will be selected for lead optimization, which will include further preclinical development and safety and toxicology assessment. Upon completion, a lead candidate and a corresponding backup will be selected to proceed into IND-enabling studies. Given the wide range of characteristics of compounds generated by the COMTi platform, we will match the proposed indication with the specific compound profile.

Upon completion of our IND-enabling studies, we plan to perform the initial clinical studies in subject subgroups with high unmet medical needs, such as individuals with schizophrenia, impulse control disorders or Parkinson's disease. While COMT inhibition may eventually find broad use in multiple neurological and psychiatric diseases, we plan to focus on indications where high COMT

activity is known to contribute to the disease process and where the Val:Val genotype has already been identified as a vulnerable population in the condition or disease state. We plan to file an IND in 2015 for our first COMTi product candidate.

Upon acceptance of this IND filing, we plan to commence two Phase 1 studies that include the measurement of biomarkers to guide further development and dose selection for later studies. Subsequently, based on the preclinical and clinical findings of the initial product candidate, other compounds can be brought into development to target other cognition-related disorders. Alternatively, the same lead product candidate could be carried forward to target other conditions.

Other Business Development Activities

Our initial program was FP01 for the treatment of acute cough and also chronic and persistent cough. FP01 is a uniquely formulated flavored chronic cough lozenge and is under development to deliver a dual mechanism of action — an immediate local soothing effect and an accelerated absorption of memantine hydrochloride working centrally at the cough reflex. Memantine hydrochloride, FP01's active ingredient, is currently approved by the FDA for the treatment of dementia associated with Alzheimer's disease. Accordingly, substantial safety and tolerability data exist for memantine hydrochloride. It has demonstrated significant cough reduction, or antitussive, effects in animal models and in exploratory human cough studies. We recently completed a Phase 2 trial of FP01 for the treatment of chronic persistent cough. FP01 was generally well tolerated and improved subject reported outcomes of cough severity. However, it did not significantly improve 24 hour cough count, the primary endpoint of the study. We may seek one or more collaborators for future development of FP01, but we do not plan to advance FP01 into additional trials without such a collaborator.

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

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, their methods of use, related technology and other inventions that are important to our business. As more fully described below, we have an issued patent covering the composition of matter and formulation of CERC-301. We have also filed multiple patent applications covering the composition of matter and use of COMT, as well as the composition of matter and use of FP01 as an antitussive. We also may rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

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

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

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

- ***CERC-301.*** We possess worldwide exclusive rights to manufacture, use and sell NR2b antagonist compounds. The CERC-301 patent portfolio consists of two 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 patents 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 (in U.S. patent only) and use claims that generically cover CERC-301. The expiration date of those patents is June 3, 2022, not including any potential patent term extension or market exclusivity period.

- ***COMT Inhibitors.*** We possess worldwide exclusive rights to manufacture, use and sell novel COMT compounds. The COMT patent portfolio includes three families of patent applications filed in the United States, Australia, Brazil, Canada, China, EPC, 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.

- ***FP01.*** We have an exclusive, worldwide license from Johns Hopkins Medical Institute to develop and market FP01 in chronic, persistent cough. Our FP01 intellectual property portfolio consists of two patent families. The first family consists of a U.S. utility and several international patent applications, directed to our proprietary FP01 technology platform and its use in treating chronic, persistent cough. The second family consists of a U.S. utility and PCT patent application directed to our first-generation compressed lozenge formulation. The composition claims in our first patent family are intended to establish FP01 utility for cough by focusing on product differentiation and on filling unmet patient needs: fast acting melts; cough syrup and combination cough products. The second patent family is intended to provide more focused protection for our initial compressed lozenge product.

The issued patent to date (U.S. patent number 8,501,816) includes composition claims protecting a uniquely formulated lozenge which provides a dual mechanism of action, delivering both an immediate local soothing effect and an accelerated absorption of memantine, centrally inhibiting the cough reflex. This patent will remain in effect in the United States through at least October 2031. The company has

filed broadly across multiple geographies and expects to receive approval for claims similar to those granted in the United States. This initial patent also serves as a building block upon which the company anticipates expanding the patent estate of FP01, including a broad range of combinations with mucolytics, antihistamines and decongestants.

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 cGMP, regulations for use in our clinical studies. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various

procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

We currently purchase the active ingredient of CERC-301 tablets, which is available from multiple sources, from one supplier. Xcelience currently manufactures the drug product for clinical testing. We intend to identify and qualify multiple manufacturers to provide the active pharmaceutical ingredient and fill-and-finish services prior to submission of a new drug application to the FDA.

In September 2013, we entered into a master contract services agreement with Pharmaceutical Research Associates, Inc., or PRA, under which PRA provides administrative, data management and statistical analysis services relating to our Clin301-201 study. Pursuant to this agreement, we have engaged PRA to be substantially responsible for overseeing and managing the conduct of the Clin301-201 study in the United States, though we remain ultimately responsible for the study and have separate agreements with the sites performing the study, other clinical research organizations and other third-party vendors. This agreement will remain in effect until the later of three years after its effective date or the completion of services by PRA. We may terminate the agreement with 30 days' notice or immediately upon a material breach of the agreement by PRA that cannot be cured. PRA may terminate the agreement immediately upon a material breach of the agreement by us that cannot be cured or, 30 days after giving notice of a curable material breach of the agreement by us, if we have not cured such breach.

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

License Agreements

Merck CERC-301 License

In March 2013, we entered into an exclusive license agreement with Merck pursuant to which Merck granted us rights relating to certain small molecule compounds which are known to inhibit or antagonize the activity of the NR2b 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 consideration of the license, we are required to make an initial aggregate payment of $1.5 million. We made an initial payment of $750,000 pursuant to the terms of the license within 45 days of the execution of the license agreement. The balance of the initial payment is due upon the later of (i) FDA acceptance of Merck preclinical data and (ii) FDA acceptance of data from a study that results in the FDA approving a Phase 3 clinical trial for an NR2b Product candidate. For each NR2b Product we develop, we are required to make milestone payments in an amount not to exceed, in the aggregate,

$40.5 million upon the achievement of various development and regulatory milestones, including first commercial sale. Additionally, we are required to make sales milestone payments in an amount not to exceed $15.0 million. Upon commercialization of an NR2b Product, we will pay Merck a royalty in the high single digits on net sales of NR2b Product. The royalty obligation will be on a product-by-product and country-by-country basis until the later of (i) the expiration of the last to expire valid patent claim of a patent licensed to us under the license agreement covering the NR2b Product in such country, and (ii) ten years from the first commercial sale of the NR2b Product in such country.

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

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

Merck COMTi License

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

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

In connection with the license grant of certain COMT compounds and COMT Products, we must grant 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 $6.5 million in milestone payments upon achievement of various development and regulatory milestones. Upon commercialization of a COMT Product, we are required to pay Merck a royalty of a low single digit on net sales of a COMT Product. The royalty obligation will be on a product-by-product and country-by-country basis until the later of (a) the expiration of the last to expire valid patent claim of a patent licensed to us under the license agreement

covering the COMT Product in such country, and (b) ten years from the first commercial sale of the COMT Product in such country.

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

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

Commercialization

We have not yet established a sales, marketing or product distribution infrastructure because our candidates are still in preclinical or early clinical development. We intend to selectively retain commercialization or co-commercialization rights in the United States for CERC-301 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 also plan to seek to commercialize any approved products outside the United States.

Competition

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

Even if we and our potential collaborators are successful in developing our product candidates, the resulting products would compete with a variety of established drugs in the areas of depression, bipolar depression, post-partum depression, schizophrenia, Parkinson's disease and impulse control disorders, or ICDs. For example, our lead product candidate, CERC-301, will compete with other drugs used as adjunctive therapies for the treatment of depression such as Abilify, marketed by Otsuka Pharmaceuticals and Bristol-Myers Squibb; Seroquel, marketed by Astra Zeneca; and buproprion, a generic drug. In addition, to our knowledge, there are five competitive programs in development that have an NMDA antagonist mechanism of action:

- Eskatamine/s-ketamine is in Phase 2 development by Johnson & Johnson, or J&J, for administration as a nasal spray;
- AZD6765, is in Phase 2 development by AstraZeneca plc, for intravenous administration;
- GLYX-13, is in Phase 2 development by Naurex Inc., or Naurex, for intravenous administration;
- NRX-1074 is in early in Phase 1 development by Naurex, for oral administration; and
- EVT 103 is in preclinical development by Evotec AG and J&J, for oral administration.

Our potential products for the treatment of schizophrenia would compete with Zyprexa, marketed by Eli Lilly and Company; Risperdal, marketed by J&J; Abilify, Seroquel, and clozapine. Zyprexa (olanzapine), Risperdal (risperidone), Seroquel (quetiapine) and Clozapine (clozaril) 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 (licensed from Orion), Rasmar (tolcapone), marketed by Valeant (licensed from Roche), and Stalevo (fixed combinations of entacapone and levodopa/carbidopa), also marketed by Novartis (licensed from Orion). Comtan, Rasmar, 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 mu-receptor antagonist, Revia (naltrexone) is approved for treating impulse control-related alcohol and opiate addictions and is marketed by Alkermes. The FDA has not approved specific medications in the treatment of ICDs; however, some medications have proven effective, including SSRI antidepressants.

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

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

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

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

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

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of 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, such as the FDA's refusal to approve pending new drug applications, or NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties.

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 cGMP, 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.

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. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions

related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

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

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 mitigate any identified or suspected serious risks, and to identify any new risks that were not apparent in clinical investigations. 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 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 cGMP 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. 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, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, or should new safety information arise, further testing requirements, FDA notification, and/or FDA review and approval may be required.

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

Moreover, under the provisions of the 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, 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 cGMP 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 being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor

may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

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

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

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. 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, and mandatory compliance programs.

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

Moreover, the recently enacted Drug Supply Chain 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 the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. 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 notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, 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.

Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations

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

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 PPACA, which, among other things, amended the intent requirement of the federal Anti-Kickback Statute and 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, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Penalties for violation of the Anti-Kickback Statute include criminal fines, imprisonment, civil penalties and damages, and exclusion from participation in federal healthcare programs.

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. 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 prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-covered, uses. In addition, 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 prosecuted 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. 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.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new 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 payors, 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, PPACA amended the intent standard for HIPAA's healthcare fraud provision 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.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. PPACA created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals, 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, imprisonment, and exclusion from Medicare. 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 attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

To the extent that any of our 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 payors 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 payors 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 payors and other governmental payors 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 payors 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 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 payors 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 payors.

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 payors, 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 payors 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 payors 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, PPACA, 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 PPACA 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. 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 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 or a decision in the infringement case that is favorable to the ANDA applicant.

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.

Foreign Regulation

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

European Union Drug Approval Process

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

Centralized procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency or EMA that is valid in all European Union member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA

by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee of Medicinal Products for Human Use, or the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

National authorization procedures

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

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

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

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

Legal Proceedings

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

Facilities

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

Employees

As of December 16, 2013, we had 17 full-time employees, 11 of whom were primarily engaged in research and development activities and seven of whom had an M.D. and/or Ph.D. degree. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

MANAGEMENT

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

Name	Age	Position
Blake M. Paterson, M.D.	56	Chief Executive Officer, President and Director
Bernadine Heather Fraser	45	Vice President, Clinical Operations and Product Management
John J. Kaiser	58	Vice President, Commercialization and Business Development
Reza Mazhari, Ph.D.	42	Vice President, Drug Discovery and Development
Federica F. O'Brien	55	Chief Financial Officer
Sharon Rowland, Ph.D.	70	Vice President, Regulatory Affairs
James Vornov, M.D., Ph.D.	56	Senior Vice President, Clinical Development and Regulatory Affairs
Sol Barer, Ph.D.	66	Chairman of the Board of Directors
Eugene A. Bauer, M.D.	71	Director
Isaac Blech	64	Vice Chairman of the Board of Directors
John Catsimatidis	65	Director
Magnus Persson, M.D., Ph.D.	53	Director
Cary W. Sucoff	61	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Appointed as a member of the Nominating and Corporate Governance Committee, effective upon the closing of this offering.

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

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

her M.S. in Pharmaceutical Sciences from the University of Montana and her Ph.D. in Pharmacology from the University of Alberta. She has also completed a post-doctoral fellowship at the Johns Hopkins University School of Medicine.

John J. Kaiser. Mr. Kaiser has served as our Vice President, Commercialization and Business Development since October 2012. Prior to joining our company, Mr. Kaiser founded Denysias Bioscience, LLC, a biopharmaceutical company focused on developing new therapies for neuropsychiatric disorders, where he served as Chief Executive Officer from February 2010 through September 2012. Mr. Kaiser has served as President of Kaiser & Associates Consulting, a boutique consulting firm providing expertise to the biopharmaceutical industry, from November 2009 to the present. From February 2008 through October 2009, Mr. Kaiser served as Vice President of Commercial and Business Development at ACADIA Pharmaceuticals Inc., or ACADIA, a specialty pharmaceutical company. Prior to ACADIA, from February 1980 to January 2008, Mr. Kaiser held positions of increasing responsibility at Eli Lilly. Mr. Kaiser received his B.S. in Pharmaceutical Sciences from the James L. Winkle College of Pharmacy at the University of Cincinnati.

Reza Mazhari, Ph.D. Dr. Mazhari has served as our Vice President, Drug Discovery and Development since September 2011. Prior to joining our company, Dr. Mazhari co-founded Cardioxyl Pharmaceuticals, Inc., a pharmaceutical company developing therapeutic agents for the treatment of cardiovascular disease, where he served as Vice President of Research and Pharmacology from October 2006 to September 2011. Dr. Mazhari is currently a part-time adjunct assistant professor of Medicine at the Johns Hopkins University. Dr. Mazhari received his B.S. and Ph.D. in Bioengineering from the University of California, San Diego.

Federica F. O'Brien, CPA. Ms. O'Brien has served as our Chief Financial Officer since April 2013. Prior to joining our company, Ms. O'Brien served as the Chief Financial Officer and Chief Operating Officer of Cervilenz Inc., a privately held medical device company, from June 2011 through April 2013, and as Director of Life Sciences for McGladrey LLP, an independent accounting firm, from February 2010 through May 2011. From July 2009 through February 2010, Ms. O'Brien provided financial and strategic consulting services. From April 2005 through July 2009, Ms. O'Brien served as the Chief Financial Officer of Cardiokine Inc., a privately held biotechnology company. Prior to 2005, Ms. O'Brien was Controller at Barrier Therapeutics, Chief Financial Officer at Infonautics, Inc. and an Audit Manager for Coopers & Lybrand. Ms. O'Brien received her B.A. in Accounting from Rutgers University and is a Certified Public Accountant in the state of New Jersey.

Sharon Rowland, Ph.D. Dr. Rowland has served as our Vice President, Regulatory Affairs since May 2011. Prior to joining our company, Dr. Rowland served as the Vice President of Regulatory Affairs & Quality, and was a member of the Executive Committee, at Alba Therapeutics from May 2005 through January 2010. She also served as an independent regulatory affairs consultant from January 2010 through April 2011. Previously, she held positions in regulatory affairs, quality and technology transfer at Aeras Global TB Vaccine Foundation, a global nonprofit biotechnology company, from May 2002 through May 2005, Globomax Inc., a pharmaceutical contract research organization and product development organization, from May 1999 through April 2002, McKesson Bioscience, a former unit of McKesson Corp., a healthcare services company, from May 1998 through April 1999, and Oncor Diagnostics, a biotechnology company, from June 1997 through April 1998. Prior to joining the industry, Dr. Rowland was an Assistant Professor at the University of Maryland School of Medicine. Dr. Rowland received her Ph.D. in microbiology from the University of Maryland Baltimore and performed post-doctoral research in the department of Medicinal Chemistry, University of Maryland School of Pharmacy. She received her B.S. in Medical Technology from the University of Maryland School of Medicine and her B.A. and M.S. in Microbiology from the University of Kansas.

James Vornov, M.D., Ph.D. Dr. Vornov has served as our Senior Vice President, Clinical Development and Regulatory Affairs since October 2012. Prior to joining our company, Dr. Vornov served as Global Therapeutic Area Leader at PAREXEL International Corporation, a biopharmaceutical

outsourcing services company, from August 2006 through October 2012. From April 1998 through August 2006, Dr. Vornov served in various capacities of increasing responsibility at Guilford Pharmaceuticals, which was acquired by MGI Pharma Inc., a biopharmaceutical company focused on oncology and acute care, including head of Experimental Medicine. For the past three years, Dr. Vornov has served as an adjunct faculty member of Johns Hopkins in the Department of Neurology and in the Brain Science Institute. Dr. Vornov received his B.A. in Biology from Columbia University. He received his M.D. and Ph.D. from Emory University School of Medicine.

Sol Barer, Ph.D. Dr. Barer has served as the Chairman of our board of directors since January 2012. Since June 2011, Dr. Barer has served as a consultant to biopharmaceutical industry participants. Prior to joining our board of directors, Dr. Barer had a variety of roles at Celgene Corporation, or Celgene, a global biopharmaceutical company, for over 35 years, until his retirement in June 2011. Dr. Barer served as Chairman and Chief Executive Officer of Celgene from May 1, 2006 until June 16, 2010. He served as Celgene's Executive Chairman from June 16, 2010 until December 31, 2010, and as its Chairman from January 2011 until June 2011. Dr. Barer received his B.S. in Chemistry from Brooklyn College of the City University of New York and his Ph.D. in Organic Chemistry from Rutgers University. Dr. Barer served on the board of Amicus Therapeutics, Inc., a biopharmaceutical company, from January 2008 to present; Aegerion Pharmaceuticals, Inc., a biopharmaceutical company, from April 2011 to present; Medgenics, Inc., or Medgenics, a medical technology and therapeutics company, from July 2012 to present; InspireMD, Inc., a medical device company, from June 2011 to present and Stratus Media Group, Inc., to be renamed RestorGenex Corporation, or RestorGenex, from November 2013 to present. Our board of directors believes that Dr. Barer's extensive experience in the biopharmaceutical industry gives him the qualifications, skills and expertise to serve on our board of directors. Furthermore, Dr. Barer's leadership abilities and experiences make him particularly well qualified to be our Chairman.

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

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

biopharmaceutical companies give him the qualifications, skills and financial expertise to serve on our board of directors.

John Catsimatidis. Mr. Catsimatidis has served on our board of directors since August 2011. Mr. Catsimatidis is the founder, Chairman and Chief Executive Officer of the Red Apple Group, Inc., a retail and energy conglomerate in the New York and Pennsylvania region, or Red Apple, which he founded in 1969 and has served in such roles since the founding. Within Red Apple, Mr. Catsimatidis has been Chairman and CEO of affiliated companies including United Refining Company since 1987, Gristedes Foods, Inc. since 1986, United Refining Energy Corp. since December 2007, United Riverhead Terminal, Inc. since November 2012, and United Metro Energy Corp. since March 2013. Mr. Catsimatidis has also served as a Director of Premier Alliance since July 2012. In 1985, Mr. Catsimatidis founded United Acquisition Corp., an investment holding company, and currently serves as the Chairman and Chief Executive Officer. Mr. Catsimatidis studied Electrical Engineering at New York University from 1966 to 1969. Our board believes that Mr. Catsimatidis's development and commercialization expertise as well as his experience in the retail and energy sectors will bring important strategic and financial insight to our board of directors.

Magnus Persson, M.D., Ph.D. Dr. Persson has served on our board of directors since August 2012. Since September 2013, Dr. Persson has served as a Director at Scandinavian Node InnoLIFE at the Karolinksa Institutet, in Stockholm, Sweden, where he also serves as an Associate Professor in Physiology, a position he has held since September 1994. Dr. Persson is a practicing pediatrician at CityAkuten in Stockholm, Sweden and has been practicing there since December 2012. He is also currently the Chief Executive Officer of C10Pharma AS in Oslo, Norway, a preclinical-stage pharmaceutical company, a position he has held since December 2012. Prior to joining our board of directors, Dr. Persson has served as a Partner at HealthCap, a Swedish-based venture capital firm, from January 2008 through December 2009, and as a Managing Partner at The Column Group, a San Francisco-based venture capital firm, from January 2010 through November 2011. From November 2011 until September 2013, Dr. Persson was a Physician at Stockholms Läns Landsting in Stockholm, Sweden. Dr. Persson founded Aerocrine AB, a medical technology company in 1994. Dr. Persson also serves on the boards of directors of Contera AS, a biotechnology company, since December 2011, Karolinska Institutet Innovations AB, a technology transfer company, since December 2011, Galecto AB, a biotechnology company, since January 2013, AscendxSpine Inc., a medical device company, since December 2012, BioWorks AB, a laboratory equipment company, since July 2013 and SLS Ventures AB, a life science venture capital firm since March 2012. Dr. Persson received his M.D. and Ph.D. in physiology from Karolinska Institutet. Our board of directors believes that Dr. Persson's extensive experience in medicine, life sciences and biotechnology financing and his experience founding and leading private as well as public biotechnology and medical technology companies make him a valuable member of our board of directors who will assist in the development of our growth strategy and business plans.

Cary W. Sucoff. Mr. Sucoff has served on our board of directors since May 2011. From February 2006 until December 2011, Mr. Sucoff owned and operated Equity Source Partners, LLC, a FINRA member firm which operated as a boutique investment bank. Since December 2011, Mr. Sucoff has owned Equity Source Partners, LLC, an advisory and consulting firm. Mr. Sucoff also serves on the board of directors of Premier Alliance, a position he has held since June 2011. Since May 2011, he has served on the board of directors of the SpendSmart Payments Company, a financial services company. Mr. Sucoff received his B.A. in History from the State University of New York, Binghamton and his J.D. from New England School of Law. Our board of directors believes that Mr. Sucoff's securities industry experience provides him with the qualifications, skills and expertise to serve on our board of directors.

Board Composition and Election of Directors

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven directors. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required. Our amended and restated bylaws will provide that our board of directors should consist of not more than 15 members and that the size of our board of directors will be determined from time to time by resolution of our board of directors. All of our directors are elected annually for a one-year term until the next annual meeting of stockholders.

The following members of our board of directors qualify as independent directors under the rules and regulations of the U.S. Securities and Exchange Commission, or SEC, and NASDAQ Stock Market, LLC, or NASDAQ.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Director Independence

Rule 5605 of the NASDAQ Marketplace Rules, or the NASDAQ Listing Rules, requires that independent directors compose a majority of a listed company's board of directors within one year of listing. In addition, the NASDAQ Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under NASDAQ Listing Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. Beginning in 2014, in addition to satisfying general independence requirements under the NASDAQ Listing Rules, members of the compensation committee must also satisfy additional independence requirements set forth in NASDAQ Listing Rule 5605(d)(2). In order to be considered independent for purposes of NASDAQ Listing Rule 5605(d)(2), a member of a compensation committee of a listed company may not, other than in his or her capacity as a member of the compensation committee, the board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries. Additionally, the board of directors of the listed company must consider whether the compensation committee member is an affiliated person of the listed company or any of its subsidiaries and, if so, must determine whether such affiliation would impair the director's judgment as a member of the compensation committee.

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

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

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

Board Leadership Structure

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

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

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

Role of the Board in Risk Oversight

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

legal and regulatory risks. While our board of directors has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on the company.

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

Committees of the Board

Our board of directors has established a standing audit committee and compensation committee, and upon the closing of this offering, we will establish a nominating and corporate governance committee. The composition and responsibilities of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board.

Audit Committee

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

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

Compensation Committee

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

The members of the compensation committee are , and serves as chair of the compensation committee. Each member of the compensation committee is a non-employee director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act, each is an outside director as defined by Section 162(m) of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and each is an independent director as defined by the NASDAQ Listing Rules, including NASDAQ Listing Rule 5605(d)(2). The compensation committee will adopted a written charter that

satisfies the applicable standards of the SEC and the NASDAQ Listing Rules, which we will post on our website upon the closing of this offering.

Nominating and Corporate Governance Committee

Upon the closing of this offering, the nominating and corporate governance committee will be responsible for making recommendations to our board of directors regarding candidates for directorships and the structure and composition of our board and the board committees. In addition, the nominating and corporate governance committee will be responsible for developing and recommending to our board corporate governance guidelines applicable to the company and advising our board on corporate governance matters.

We expect that the members of the nominating and corporate governance committee will be and will serve as chair of the nominating and corporate governance committee. Each member of the nominating and corporate governance committee will be an independent director as defined by the NASDAQ Listing Rules. The nominating and corporate governance committee will adopt a written charter that satisfies the applicable standards of the NASDAQ Listing Rules effective upon the closing of this offering and which we will post on our website upon the closing of this offering.

Code of Business Conduct and Ethics

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

Compensation Committee Interlocks and Insider Participation

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

EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2013 Summary Compensation Table" below. In 2013, our chief executive officer and our two other highest-paid executive officers, or our named executive officers, were as follows:

- Blake M. Paterson, M.D., President and Chief Executive Officer
- James Vornov, M.D., Ph.D., Senior Vice President, Clinical Development and Regulatory Affairs
- John Kaiser, Vice President, Commercialization and Business Development

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

2013 Summary Compensation Table

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

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	All Other Compensation ($)	Total ($)
Blake M. Paterson, M.D. President and Chief Executive Officer	2013	$ 325,000		—	$ 218(3)	
James Vornov, M.D., Ph.D. Senior Vice President, Clinical Development and Regulatory Affairs	2013	300,000		—	218(4)	
John Kaiser Vice President, Commercialization and Business Development	2013	285,000		40,360	129,381(5)	

(1) The amounts reflect the discretionary bonus paid in 2014 for performance during 2013, as discussed further below under the Narrative to Summary Compensation Table, under the heading "Annual Bonus."

(2) The amounts reflect the grant date fair value for option awards granted during 2013 in accordance with FASB Topic ASC 718. Mr. Kaiser will only realize compensation to the extent the market price of our common stock is greater than the exercise price of such option award. For a detailed description of the assumptions used for purposes of determining the grant date fair value, see Note 10 to the financial statements included elsewhere in this prospectus.

(3) Amount consists of $218 for the premium amount paid by us for life insurance.

(4) Amount consists of $218 for the premium amount paid by us for life insurance.

(5) Amount consists of a reimbursement of Mr. Kaiser's temporary living expenses for up to six months totaling an aggregate amount of $29,163, a one-time relocation bonus of $100,000 for Mr. Kaiser and $218 for the premium amount paid by us for life insurance.

Narrative to Summary Compensation Table

We review compensation annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market based on Radford data for private companies with a 25% target for 2013, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives.

Our board of directors has historically determined our executives' compensation. Our compensation committee typically reviews and discusses management's proposed compensation with the chief executive officer for all executives other than the chief executive officer. Based on those discussions and its discretion, the compensation committee then recommends the compensation for each executive officer. Our board of directors, without members of management present, discusses the compensation committee's recommendations and ultimately approves the compensation of our executive officers. To date, our compensation committee has used a compensation consultant from Radford who used Radford data for privately held, similarly sized, biotech companies for purposes of determining executive compensation. The compensation committee has used the 50th percentile for the 2013 fiscal year for bonus and equity and 25th for base salary, with a plan to move to the 50th percentile for the 2014 fiscal year for all compensation. Prior to the closing of this offering, we expect to engage a compensation consultant to assist us in establishing a peer group of companies

Annual Base Salary

The following table presents the base salaries for each of our named executive officers for the 2013 and 2014 fiscal years. The 2014 base salaries for all of the named executive officers are expected to be reviewed in February 2014 and the compensation committee may make adjustments at such time.

Name	2013 Base Salary ($)	2014 Base Salary ($)
Blake M. Paterson, M.D.	325,000	
James Vornov, M.D., Ph.D.	300,000	
John Kaiser	285,000	

Annual Bonus

Our discretionary bonus plan motivates and rewards our executives for achievements relative to our goals and expectations for each fiscal year. Each named executive officer has a target bonus opportunity, defined as a percentage of his annual salary. Following the end of each year, our board of directors determines bonuses, which can be in excess of the target bonus opportunity. Material considerations in determining bonuses include our financial performance relative to our plan and achievement of corporate objectives for the year; the executive's handling of unplanned events and opportunities; and the chief executive officer's input with respect to the performance of the company and of our executives, other than himself. Based on these factors and in the sole discretion of our board of directors, we approved the following bonuses in 2014 for our named executive officers for 2013.

Name	Target Bonus (% of salary)	Actual Bonus ($)	Actual Bonus (% of salary)
Blake M. Paterson, M.D.	40%		
James Vornov, M.D., Ph.D.	27.5%		
John Kaiser	25%		

Long-Term Incentives

Our 2011 Stock Incentive Plan authorizes us to make grants to eligible recipients of non-qualified stock options, incentive stock options, restricted stock awards, restricted stock units and other forms of awards, such as stock appreciation rights. While we have made restricted stock awards to our executive officers in the past, our equity grants during 2013 to our executive officers were only in the form of stock options.

Other Compensation

All amounts shown in the "All Other Compensation" column in the Summary Compensation Table relate to premiums paid by us for life insurance policies for Mr. Paterson, Mr. Vornov and Mr. Kaiser and amounts paid by us to reimburse Mr. Kaiser for temporary living expenses and a one-time relocation bonus.

Employment Arrangements

Please see " — Offer Letters" for information regarding the employment and severance agreements for each of our named executive officers.

Outstanding Equity Awards at 2013 Fiscal Year End Table

The following table presents information regarding all outstanding stock options held by each of our named executive officers on December 31, 2013.

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Blake M. Paterson, M.D.	5/8/2012	1,000,000	2,000,000(1)	0.31	2/28/2022
James Vornov, M.D., Ph.D.	11/9/2012	133,333	266,667(2)	0.31	10/31/2022
John Kaiser	11/9/2012	133,333	266,667(2)	0.31	10/31/2022
	8/29/2013	—	200,000(3)	0.32	5/31/2023

(1) Such stock option vests in equal annual installments commencing on February 24, 2012 through February 24, 2015.

(2) Such stock option vests in equal annual installments commencing on October 15, 2012 through October 15, 2015.

(3) Such stock option vests in equal annual installments commencing on May 6, 2013 through May 5, 2016.

Offer Letters

Blake M. Paterson, M.D.

Dr. Paterson entered into an offer letter with the company effective May 1, 2011. The offer letter provides for an annual base salary of $250,000, with an automatic increase to $275,000, effective May 1, 2012, and another automatic increase to $300,000, effective May 1, 2013. Dr. Paterson's annual base salary may be further increased from time to time. Dr. Paterson's base salary as of December 31, 2013 was $325,000. Upon execution of the offer letter, Dr. Paterson was entitled to receive a $100,000 signing bonus. In addition, Dr. Paterson is eligible to receive a discretionary annual bonus as determined by our board of directors or the compensation committee of the board, referred to the compensation committee,

in its sole discretion, provided that Dr. Paterson is employed by the company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid to chief executive officers of similarly situated companies in the biotechnology industry, subject to corporate and individual performance. The offer letter provides that Dr. Paterson agreed to purchase 3,000,000 shares of restricted common stock, which restricted stock was subject to vesting as to one third of the shares on May 1 of each of 2012, 2013 and 2014, subject to Dr. Paterson's continued employment on the applicable vesting dates and the terms of the 2011 Stock Incentive Plan. However, in September 2011, the restrictions were modified so that all of the shares vested at that time.

Pursuant to the terms of Dr. Paterson's offer letter, if Dr. Paterson's employment is terminated for any reason, then the company will pay Dr. Paterson his base salary, bonus and expenses accrued, but unpaid as of the date of his termination, and any benefits accrued and due under any applicable benefit plans and programs of the company.

If Dr. Paterson's employment is terminated on account of his death or disability, and provided that Dr. Paterson complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company in the case of termination on account of disability, he will be entitled to a pro rata average bonus, which for purposes of the offer letter means the average of the annual full-year cash bonuses he received from the company for the three completed calendar years prior to termination (or fewer full year periods if the employment term is less than three years, with 2011 being deemed a full year of service and any prorated bonus paid for 2011 being adjusted upward for the full year for purposes of such calculation), prorated for the portion of the year in which such termination occurred, paid over 12 equal monthly installments.

If Dr. Paterson's employment is terminated by the company without cause or by Dr. Paterson for good reason, provided he complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company, Dr. Paterson is entitled to an amount equal to the sum of (i) 12 months of his then-current base salary and (ii) a pro rata average bonus, payable in 12 equal monthly installments. In addition, Dr. Paterson is entitled to company-paid COBRA premiums for 12 months or until he is eligible for substantially equal coverage, and full vesting of the restricted stock award purchased in connection with his commencement of employment and any future stock option or stock award.

The offer letter provides that at all times during Dr. Paterson's employment and thereafter, Dr. Paterson will maintain the confidentiality of all confidential information obtained by him as a result of his employment with the company, assign all inventions and not disparage the company or any of its officers, directors, employees, shareholders or products. In addition, during the term of Dr. Paterson's employment with the company, and for the 12 month period after Dr. Paterson's termination of employment, Dr. Paterson cannot (i) compete against the company, (ii) interfere with the relationships between the company and any of its subsidiaries, affiliates or any of their respective vendors or licensors, or (iii) recruit in any way the employees of the company.

James Vornov, M.D., Ph.D.

Dr. Vornov entered into an offer letter with the company effective October 15, 2012. The offer letter provides for an annual base salary of $300,000, which, beginning February 2014, will be reviewed annually and may be increased by our board of directors. Dr. Vornov is eligible to receive a discretionary annual bonus as determined by our board of directors or the compensation committee, in its sole discretion, provided that Dr. Vornov is employed by the company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid the executives of similar grade of similarly situated companies on the biotechnology industry, subject to corporate and individual performance. In addition, the offer letter provides that, subject to approval by our board of directors, Dr. Vornov will receive a stock option to

purchase 400,000 shares of common stock, which is subject to vesting as to one third of the shares on October 15 of each of 2013, 2014 and 2015, subject to Dr. Vornov's continued employment on the applicable vesting dates and the terms of the 2011 Stock Incentive Plan.

Pursuant to the terms of Dr. Vornov's offer letter, if Dr. Vornov's employment is terminated for any reason, then the company will pay Dr. Vornov his base salary, bonus and expenses accrued, but unpaid as of the date of his termination, and any benefits accrued and due under any applicable benefit plans and programs of the company.

If Dr. Vornov's employment is terminated by the company without cause or by Dr. Vornov for good reason, provided he complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company, Dr. Vornov is entitled to an amount equal to six months of his then-current base salary, payable in six equal monthly installments. In addition, Dr. Vornov is entitled to company-paid COBRA premiums for 12 months or until he is eligible for substantially equal coverage, and full vesting of the stock option award.

The offer letter provides that at all times during Dr. Vornov's employment and thereafter, Dr. Vornov will maintain the confidentiality of all confidential information obtained by him as a result of his employment with the company, assign all inventions and not disparage the company or any of its officers, directors, employees, shareholders or products. In addition, during the term of Dr. Vornov's employment with the company, and for the 12 month period after Dr. Vornov's termination of employment, Dr. Vornov cannot (i) compete against the company, (ii) interfere with the relationships between the company and any of its subsidiaries, affiliates or any of their respective vendors or licensors, or (iii) recruit in any way the employees of the company.

John Kaiser

Mr. Kaiser entered into an offer letter with the company effective October 15, 2012. The offer letter provides for an annual base salary of $285,000. Mr. Kaiser's annual base salary may be further increased from time to time. In connection with Mr. Kaiser's commencement of employment, he was entitled to reimbursement of temporary living expenses up to six months, and a relocation bonus of $100,000. A pro-rata portion of the relocation bonus must be repaid to the company if his employment is terminated for cause or he resigns voluntarily within 18 months after commencement of employment. Mr. Kaiser is eligible to receive a discretionary annual bonus as determined by our board of directors or the compensation committee, in its sole discretion, provided that Mr. Kaiser is employed by the company on the applicable bonus payment date. Such annual discretionary bonus may be paid in the form of cash or equity awards, consistent with bonuses paid the executives of similar grade of similarly situated companies on the biotechnology industry, subject to corporate and individual performance. In addition, the offer letter provides that, subject to approval by our board of directors, Mr. Kaiser will receive a stock option to purchase 400,000 shares of common stock, which is subject to vesting as to one third of the shares on October 15 of each of 2013, 2014 and 2015, subject to Mr. Kaiser's continued employment on the applicable vesting dates and the terms of the 2011 Stock Incentive Plan.

Pursuant to the terms of Mr. Kaiser's offer letter, if Mr. Kaiser's employment is terminated for any reason, then the company will pay Mr. Kaiser his base salary, bonus and expenses accrued, but unpaid as of the date of his termination, and any benefits accrued and due under any applicable benefit plans and programs of the company.

If Mr. Kaiser's employment is terminated by the company without cause or by Mr. Kaiser for good reason, provided he complies with the restrictive covenants set forth in the offer letter and executes and does not revoke a release of claims in favor of the company, Mr. Kaiser is entitled to an amount equal to 12 months of his then-current base salary, payable in 12 equal monthly installments. In addition, Mr. Kaiser is entitled to company-paid COBRA premiums for 12 months or until he is eligible for substantially equal coverage, and full vesting of the stock option award.

The offer letter provides that at all times during Mr. Kaiser's employment and thereafter, Mr. Kaiser will maintain the confidentiality of all confidential information obtained by him as a result of his employment with the company, assign all inventions and not disparage the company or any of its officers, directors, employees, shareholders or products. In addition, during the term of Mr. Kaiser's employment with the company, and for the 12 month period after Mr. Kaiser's termination of employment, Mr. Kaiser cannot (i) compete against the company, (ii) interfere with the relationships between the company and any of its subsidiaries, affiliates or any of their respective vendors or licensors, or (iii) recruit in any way the employees of the company.

For purposes of the offer letters, termination for "good reason" generally means a termination initiated by the employee in response to one or more of the following events: (i) a material diminution in the employee's duties, authorities or responsibilities, (ii) a requirement by the company that the employee's principal place of work be permanently moved to a location more than 50 miles away from Baltimore, Maryland, or (iii) the company material breach of the offer letter, including a diminution of base salary. In order for a termination to be on account of good reason, the employee must notify the company of his intention to terminate for good reason, the company has an opportunity to cure the action or omission that constitutes the ground for good reason and the named executive officer must terminate employment for good reason shortly after the end of the company's cure period. In addition, Mr. Kaiser may invoke good reason in the event that the company fails to nominate him as a member of our board of directors. The employee is required to provide the company with a written notice detailing the specific circumstances alleged to constitute good reason within 30 days after the first occurrence of such circumstances, and the company shall have 30 days following the receipt of such notice to cure the alleged good reason event.

Termination for "cause" generally includes the following: (i) the employee's willful misconduct or gross negligence in the performance of his duties to the company not cured within 30 days after notice, (ii) the employee's failure to perform his duties to the company or to follow the lawful directives of our board of directors that is not cured within 30 days after notice, (iii) the employee's commission of, indictment for, conviction of, or pleading of guilty or nolo contendere to, a felony or any crime involving moral turpitude, or (iv) any act of theft, fraud, malfeasance or dishonesty in connection with the performance of the employee's duties to the company, or (v) a material breach of the offer letter or any other agreement with the company, or a material violation of the company's code of conduct or other written policy that is not cured within 30 days after notice.

Stock Incentive Plans

2011 Stock Incentive Plan

Our board of directors and stockholders adopted the 2011 Stock Incentive Plan on April 28, 2011. The 2011 Stock Incentive Plan was amended on January 10, 2012 and on May 6, 2013 to increase the number of shares authorized for issuance thereunder. We expect to adopt a new equity compensation plan, the 2014 Equity Incentive Plan, prior to the closing of this offering. We expect our stockholders will approve the 2014 Equity Incentive Plan and it will become effective upon the execution and delivery of the underwriting agreement for this offering.

Types of Stock Awards

The 2011 Stock Incentive Plan provides for the grant of stock options (incentive stock options, or ISOs, and non-qualified stock options, or NSOs), restricted stock awards and other stock-based awards, which are collectively referred to as stock awards. Other stock-based awards are awards of common stock and other awards (including cash) that are valued in whole or in part by reference to, or are payable in or otherwise based on, our common stock and may include, without limitation, restricted stock units, performance share awards or an award valued by reference to an affiliate of the company. Stock awards

may be granted to employees, including officers, non-employee directors and consultants of the company or our affiliates, except that ISOs may be granted only to employees.

Share Reserve

The aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2011 Stock Incentive Plan is 19,724,005 shares. If a stock award granted under the 2011 Stock Incentive Plan expires, terminates, is canceled or is forfeited for any reason, the number of shares subject to the stock award will again be available for purposes of stock awards under the 2011 Stock Incentive Plan. In addition, if stock awards are settled in cash, the share reserve will be reduced by the number of shares of common stock with a value equal to the amount of the cash distributions as of the time that such amount was determined and if stock options are exercised using net exercise, the share reserve will be reduced by the gross number of shares of common stock subject to the exercised portion of the option. As of September 30, 2013, 5,987,375 shares have been granted under the 2011 Stock Incentive Plan and 4,700,000 shares have been granted outside of the 2011 Stock Incentive Plan.

Administration

Our board of directors or a duly authorized committee thereof, has the authority to administer the 2011 Stock Incentive Plan. Subject to the terms of the 2011 Stock Incentive Plan, our board of directors or the authorized committee, referred to herein as the committee, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the committee will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award. The committee has the authority to modify outstanding awards under the 2011 Stock Incentive Plan. The committee has the authority to adopt, alter and repeal administrative rules, guidelines and practices governing the 2011 Stock Incentive Plan and to perform all other acts, including delegating administrative responsibilities, as it deems advisable to construe and interpret the terms and provisions of the 2011 Stock Incentive Plan and any stock award granted under the 2011 Stock Incentive Plan. Decisions and interpretations or other actions by the committee are in the discretion of the committee and are final binding and conclusive on the company and all participants in the 2011 Stock Incentive Plan.

Stock Options

ISOs and NSOs are granted pursuant to stock option agreements adopted by the committee. The committee determines the exercise price for a stock option, within the terms and conditions of the 2011 Stock Incentive Plan, provided that the exercise price of a stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2011 Stock Incentive Plan will become exercisable at the rate specified by the committee and may be exercisable for restricted stock, if determined by the committee.

The committee determines the term of stock options granted under the 2011 Stock Incentive Plan, up to a maximum of ten years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, or voluntary resignation, the option holder may generally exercise any vested options for a period of 90 days following the cessation of service. If the options holder's service relationship terminates due to voluntary resignation, the option holder may generally exercise any vested options for a period of 30 days following cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an option holder's service relationship with us or any of our affiliates ceases due to disability or death, or an option holder dies within a certain period following cessation of service, the option holder or a beneficiary may generally exercise any vested options for a period of one year following the option holder's disability or death. Unless

otherwise provided by the committee at the time a stock option is granted, in the event of a termination for cause, or the participant violates certain restrictive covenants, including but not limited to, nondisclosure of confidential information, non-solicitation, non-competition and non-disparagement provisions set forth in the 2011 Stock Incentive Plan, referred to as detrimental activity, in any case, before the stock option is exercised, then the stock option will terminate. If an option holder engages in detrimental activity within one year following the later of the date the stock option is exercised or becomes vested, then option holder must pay back to the company any gain realized as a result of exercise. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the committee and may include (i) cash, check, bank draft or money order, (ii) if the company's common stock is publicly traded, a broker-assisted cashless exercise, or (iii) such other methods as may be approved by the committee, including without limitation, the tender of shares of our common stock previously owned by the option holder or a net exercise of the option.

Unless the committee provides otherwise, options generally are not transferable except by will, the laws of descent and distribution. The committee may provide that an NSO may be transferred to a family member, as such term is defined under the applicable securities laws.

The committee may at any time offer to buy out a stock option previously granted, based on the terms established by the committee and communicated to the option holder at the time the offer is made.

Tax Limitations on Incentive Stock Options

The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards

Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the committee. Restricted stock awards may be granted for a purchase price, or no purchase price, and either alone or in addition to other stock awards granted under the 2011 Stock Incentive Plan. The committee determines the purchase price, if any, the vesting schedule, if any, and he rights to acceleration of any vesting schedule, and all other terms and conditions of each restricted stock award. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the committee. Rights to acquire shares under a restricted stock award may not be transferred. Except as otherwise provided in the applicable award agreement, restricted stock unit awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Unless otherwise provided by the committee at the time a restricted stock award is granted, in the event a participant engages in detrimental activity prior to or during the one year period after the vesting of restricted stock, the committee may direct that all unvested restricted stock will be immediately forfeited and that the participant must pay to the company an amount equal to the fair market value at the time of vesting of any restricted stock that vested prior to the participant's engagement in the detrimental activity. If an option holder engages in detrimental activity within one year following the later of the date the stock option is exercised or becomes vested, then option holder must pay back to the company any gain realized as a result of exercise. In no event may an option be exercised beyond the expiration of its term.

Other Stock Awards

The committee may grant other awards based in whole or in part by reference to our common stock. The committee will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure

In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (i) the aggregate number and kind of shares that may be issued under the 2011 Stock Incentive Plan, (ii) the number and/or kind of shares or other property (including cash) that can be issued upon exercise of an outstanding stock award or under other stock awards granted under the plan, and (iii) the purchase price thereof.

Acquisition Event

In the event of an acquisition event, the committee may terminate all outstanding and unexercised stock options or any other stock-based award that provides for a participant to exercise the stock award, effective as of the date of the acquisition event, by delivering notice of termination to each participant at least 20 days prior to the date of consummation of the event. The participant may exercise the stock awards during the notice period, contingent upon the occurrence of the acquisition event, to the extent vested (or without regard to limitation of exercisability, as determined by the committee). All such stock awards not exercised will be forfeited in connection with the acquisition event. The committee retains the right to terminate any such exercisable stock award for which the exercise price is equal to or exceeds the fair market value without payment of consideration therefor.

For purposes of the 2011 Stock Incentive Plan, an acquisition event is a merger or consolidation in which the company is not the surviving entity, any transaction that results in the acquisition of all or substantially all of the company's outstanding common stock by a single person or entity or by a group of persons and/or entities acting in concert, or the sale or transfer of all or substantially all of the company's assets.

Change of Control

In the event of a change of control, the committee has the discretion to take any of the following actions with respect to stock awards:

- arrange for the substitution of a stock award by a surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award; or
- cancel stock awards for fair value, which, in the case of options, may equal the excess, if any, of (a) the value of the property to be received in the change of control to holders of the same number of shares of common stock subject to the stock option, over (b) the exercise price otherwise payable in connection with the stock award.

The committee is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2011 Stock Incentive Plan, a change of control is generally (i) the acquisition by a person or entity, other than a corporation owned directly or indirectly by the stockholders of the company in substantially the same proportions as their ownership of stock of the company, of more than 50% of our combined voting power; (ii) a consummated merger, or consolidation, other than a merger or consolidation which would result in the voting securities of the company outstanding immediately prior thereto continuing to represent the total voting power represented by the voting securities of the company or such surviving entity outstanding immediately after such merger or consolidation; (iii) a

consummated sale or other disposition of all or substantially of our assets; or (iv) the dissolutions, liquidation or winding up of the company.

Company Call Rights; Right of First Refusal; Approved Sale

Upon termination of employment or service, the company has certain call rights with respect to our common stock obtained through exercise of stock options, through restricted stock or other stock-based awards. The company's purchase price is based on the reason for the participant's termination. In addition, the company has rights of first refusal in the event a participant desires to transfer shares obtained pursuant to an awards under the 2011 Stock Incentive Plan. If the board of directors and stockholders having the requisite voting power at law and under the company's governing documents approve a sale of all or substantially all of the assets of the company or a sale of all or substantially all of the shares of common stock to an independent third party or group of independent third parties, then each holder of shares of common stock issued pursuant to an award under the 2011 Stock Incentive Plan is required to vote for, consent to and raise no objections to such sale, and generally shall be subject to the same terms and restrictions as the other stockholders participating in the sale, referred to as drag-along rights. The company's call rights, right of first refusal and drag-along rights terminate upon the first to occur of the date that the company sells its common stock in a bona fide underwriting pursuant to a registration statement under the Securities Act of 1933, as amended, or the Securities Act, or the date that any class of common equity securities of the company is required to be registered under Section 12 of the Exchange Act.

Amendment and Termination

Our board of directors or the committee has the authority to amend, suspend, or terminate the 2011 Stock Incentive Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Unless approved by stockholders, if required, no amendment may increase shares of our common stock available for issuance under the 2011 Stock Incentive Plan, change the classification of individuals eligible to receive stock awards under the 2011 Stock Incentive Plan, decrease the minimum exercise price of stock options, extend the maximum stock option term or require stockholder approval in order to continue to comply with the rules under the Code for ISOs.

401(k) Plan

Our named executive officers participate in our broad-based 401(k) savings plan offered to all full time employees of the company. There is no mandatory matching or other employer contribution provided by the company during the year. Annually, the benefits committee determines if a discretionary match or other discretionary employer contribution is to be made. If made, any discretionary match or other employer contribution will vest over a six-year graded vesting schedule so that 20% vests each year of service. Vesting is accelerated upon death, disability and termination of the plan. Employees can designate the investment of their 401(k) accounts from among a broad range of mutual funds. We do not allow investment in our common stock through the 401(k) plan.

Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation, which will become effective upon the closing of this offering, limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;

- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for voting or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the Delaware General Corporation Law is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the Delaware General Corporation Law.

In addition, our certificate of incorporation, which will become effective upon the closing of this offering, provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into indemnification agreements with all of our directors, and we intend to enter into indemnification agreements with all of our executive officers prior to the closing of this offering. These indemnification agreements may require us, among other things, to indemnify each such director and executive officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him in any action or proceeding arising out of his or her service as one of our directors or executive officers.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Non-Employee Director Compensation

During the 2013 fiscal year, we have paid our non-employee directors a fee for their service as a director. We also reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending board of director and committee meetings or otherwise in direct service of our company.

The table below shows all compensation to our non-employee directors during 2013.

Name	Fees Earned or Paid in Cash	Total ($)
Sol Barer, Ph.D.	$ 33,500	$ 33,500
Eugene A. Bauer, M.D.	27,000	27,000
Isaac Blech	29,000	29,000
John Catsimatidis	21,000	21,000
Magnus Persson, M.D., Ph.D.	26,000	26,000
Cary W. Sucoff	31,000	31,000

Non-Employee Director Equity Outstanding at 2013 Fiscal Year End

The following table provides information about outstanding stock options and stock awards held by each of our non-employee directors as of December 31, 2013. All of these options and awards were granted under our 2011 Stock Incentive Plan.

	Option Awards
	Number of Securities Underlying Unexercised Options (#) Exercisable
Sol Barer, Ph.D.	800,000
Eugene A. Bauer, M.D.	—
Isaac Blech	500,000
John Catsimatidis	—
Magnus Persson, M.D., Ph.D.	—
Cary W. Sucoff	66,666

We expect that prior to the closing of this offering, our board of directors will adopt a non-employee director compensation policy that will be effective upon the closing of this offering which will include an annual base retainer, fees for service on committees.

TRANSACTIONS WITH RELATED PERSONS

The following is a description of transactions since inception to which we have been a party, and in which any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, or affiliates or immediate family members of any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, had or will have a direct or indirect material interest. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, from unrelated third parties.

Convertible Preferred Stock Financings

In August 2013, we entered into a Series A-1 Preferred Stock and Warrant Purchase Agreement pursuant to which we issued and sold to investors at a purchase price of $0.75 per unit an aggregate of 9,074,511 shares of Series A-1 convertible preferred stock and warrants to purchase 2,268,573 shares of our common stock at $1.00 per share which is subject to adjustment as set forth in such warrant. The aggregate consideration for the Series A-1 convertible preferred stock offering was $6.8 million in cash. The following table sets forth the shares of Series A-1 convertible preferred stock and warrants issued to our directors, executive officers and holders of more than five percent of our capital stock and their affiliates, and the breakdown of the purchase price paid:

Name	Shares of Series A-1 Convertible Preferred Stock Purchased	Shares of Common Stock Issuable Upon Exercise of Warrants	Aggregate Purchase Price
Directors:			
Sol Barer, Ph.D.	53,334	13,333	$ 40,000

From February 2012 through May 2012, we entered into Series A Preferred Stock and Warrant Purchase Agreements pursuant to which we issued and sold to investors at a purchase price of $0.75 per unit an aggregate of 31,116,391 shares of Series A convertible preferred stock and warrants to purchase 7,779,090 shares of our common stock at $1.00 per share. The aggregate consideration for the Series A convertible preferred stock offering was $20.2 million in cash and $3.1 million in aggregate principal and interest due under a convertible demand promissory note held by an affiliate of Mr. Blech, a member of our board of directors, which pursuant to the terms of such note, was converted into shares of Series A convertible preferred stock. In addition, for any investor of Series A convertible preferred stock who also participated in the Series A-1 convertible preferred stock offering, we amended the terms of the original warrants issued in connection with such Series A convertible preferred stock by reducing the exercise price of the warrants issued from $1.00 per share of common stock to $0.50 per share of common stock provided that such investor purchased a minimum of 40% of their original Series A convertible preferred stock investment. The following table sets forth the shares of Series A convertible preferred stock and

warrants issued to our directors, executive officers and holders of more than five percent of our capital stock and their affiliates, and the breakdown of the purchase price paid:

Name	Shares of Series A Convertible Preferred Stock Purchased	Shares of Common Stock Issuable Upon Exercise of Warrants	Aggregate Purchase Price
5% Stockholders:			
Daniel Blech Trust DTD 8/3/2005(1)	4,077,475	1,019,369	$ 0(2)
Directors:			
Sol Barer, Ph.D.	133,333	33,333	$ 100,000
Isaac Blech(3)	4,210,808	1,052,701	$ 3,158,106
John Catsimatidis(4)	400,000	100,000	$ 300,000

(1) Mr. Blech has voting control over these shares — see footnote 3 below.

(2) Received upon the conversion of a demand promissory note. See "Loan Transaction" below.

(3) These numbers include the (i) 4,077,475 shares of Series A convertible preferred stock held by Daniel Blech Trust DTD 8/3/2005, or the Blech Trust, and (ii) 1,019,369 common shares issuable upon the exercise of warrants held by the Blech Trust.

(4) Represents Series A convertible preferred stock and warrants held by United Acquisition Corp., which is indirectly 100% owned and controlled by Mr. Catsimatidis.

Loan Transaction

On April 29, 2011, we executed a convertible demand promissory note with an affiliate of Mr. Blech, a member of our board of directors, which was drawn on from April through November 2011 in an aggregate principal amount of $3.0 million. The note carried interest at a rate of 3% per annum, compounded quarterly. On March 23, 2012, the principal outstanding under the convertible demand promissory note, plus accrued and unpaid interest of $58,000 was converted into 4,077,475 shares of Series A convertible preferred stock and a warrant to purchase 1,019,369 shares of our common stock at an exercise price of $1.00 per share.

FP01 Agreement

Dr. Paterson owns a 50% equity interest in Fells Laboratories LLC, or Fells. In May 2011, we entered into an agreement with Fells pursuant to which we obtained certain assets of Fells relating to FP01, including three patents and a license agreement with Johns Hopkins University. We have paid an aggregate of $540,000 to Fells pursuant to the terms of the agreement, which consisted of a $340,000 upfront payment in May 2011 and a $200,000 milestone payment in July 2012 upon the successful completion of the prototype of the formulation of FP01. The company could be required to pay up to an additional $2.9 million to Fells upon the achievement of certain contingent development and regulatory milestones. We do not expect to pay any additional fees to Fells unless we are able to out-license FP01 to a third party for development.

Offer Letters

We currently have written offer letters with our President and Chief Executive Officer, Dr. Blake Paterson, our Vice President, Commercialization and Business Development, John Kaiser, and our Senior Vice President, Clinical Development and Regulatory Affairs, Dr. James Vornov. For more information, refer to the section entitled "Executive Compensation — Offer Letters."

Stock Options Granted to Executive Officers and Directors

We have granted stock options under our 2011 Stock Incentive Plan and outside of such plan to our executive officers and directors. The table below summarizes the stock option grants made to such persons since inception.

Optionee Name	Grant Date	Price Per Share	Shares Issued
Blake M. Paterson, M.D.	5/8/12	$ 0.31	3,000,000
Sharon Rowland, Ph.D.	5/20/11	$ 0.01	200,000
Sharon Rowland, Ph.D.	5/8/12	$ 0.31	100,000
Sharon Rowland, Ph.D.	2/4/13	$ 0.31	100,000
Reza Mazhari, Ph.D.	9/6/11	$ 0.20	100,000
Reza Mazhari, Ph.D.	5/8/12	$ 0.31	200,000
Reza Mazhari, Ph.D.	2/4/13	$ 0.31	135,000
Sol J. Barer, Ph.D.	1/10/12	$ 0.20	2,400,000
James Vornov, M.D., Ph.D.	11/9/12	$ 0.31	400,000
John J. Kaiser	11/9/12	$ 0.31	400,000
John J. Kaiser	8/29/13	$ 0.32	200,000
Federica F. O'Brien	8/29/13	$ 0.32	750,000
Isaac Blech	5/8/12	$ 0.31	1,500,000
Cary W. Sucoff	5/8/12	$ 0.31	200,000
Total			9,685,000

For further information regarding stock option grants to our executive officers and directors, see the section entitled "Executive Compensation."

Restricted Stock Grants to Executive Officers and Directors

We issued 3,000,000 restricted shares (drawn from 2011 Stock Incentive Plan) to Dr. Paterson, our President and Chief Executive Officer in April 2011. The fair value associated with these restricted shares was approximately $3,000 and vested over a three-year period. In September 2011, the shares were modified to become fully vested.

Registration Rights

We are a party to an Amended and Restated Investors' Rights Agreement with the holders of our convertible preferred stock, including some of our 5% stockholders and their affiliates and entities affiliated with our directors. This agreement provides these holders the right, following the closing of this offering, to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing. See "Description of Capital Stock — Registration Rights" for additional information regarding these registration rights.

Policies and Procedures for Related Person Transactions

In connection with this offering, our board of directors plans to adopt a written related person transaction policy to set forth policies and procedures for the review and approval or ratification of related person transactions. Effective upon the closing of this offering, this policy is expected to cover any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, the amount involved exceeds $120,000, and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person," had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or

entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our audit committee. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chairman of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity whether or not the person is also a director of the entity, that is a participant in the transaction, where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of $200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and
- a transaction that is specifically contemplated by provisions of our certificate of incorporation or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee's charter.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it has been the practice of our board of directors to consider the nature of and business reason for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of the company, or not contrary to, our best interests. In addition, all related person transactions required prior approval, or later ratification, by our board of directors.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of December 1, 2013 by:

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

The column entitled "Percentage of Shares Beneficially Owned — Before Offering" is based on a total of shares of our common stock outstanding as of , assuming the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of shares of our common stock upon the closing of this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. The column entitled "Percentage of Shares Beneficially Owned — After Offering" is based on shares of our common stock to be outstanding after this offering, including the shares of our common stock that we are selling in this offering, but not including any additional shares issuable upon exercise of outstanding options. The percentage ownership information assumes no exercise of the underwriters' over-allotment option to purchase additional shares.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days after December 1, 2013 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to

applicable community property laws, where applicable. Except as otherwise set forth below, the address of each beneficial owner is c/o Cerecor Inc., 400 E Pratt Street, Suite 606, Baltimore, Maryland 21202.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% Stockholders:			
Daniel Blech Trust DTD 8/3/2005(1)	5,096,844		
Directors and Named Executive Officers:			
Blake M. Paterson, M.D.(2)	4,000,000		
James Vornov, M.D., Ph.D.(3)	133,333		
John Kaiser(4)	133,333		
Sol Barer, Ph.D.(5)	2,433,333		
Eugene A. Bauer, M.D.(6)	750,000		
Isaac Blech(7)	11,293,510		
John Catsimatidis(8)	1,000,000		
Magnus Persson, M.D., Ph.D.	—		
Cary W. Sucoff(9)	566,667		
All current executive officers and directors as a group (12 persons)(10)	20,288,510		

(1) Consists of (i) 4,077,475 shares of common stock issuable upon the automatic conversion of 4,077,475 shares of Series A convertible preferred stock and (ii) 1,019,369 shares of common stock issuable upon the exercise of warrants within 60 days of December 1, 2013. Isaac Blech has voting control over all of these shares — see footnote 7 below.

(2) Consists of (i) 3,000,000 shares of common stock, and (ii) 1,000,000 shares of common stock issuable upon the exercise of options within 60 days of December 1, 2013.

(3) Consists of 133,333 shares of common stock issuable upon the exercise of options within 60 days of December 1, 2013.

(4) Consists of 133,333 shares of common stock issuable upon the exercise of options within 60 days of December 1, 2013.

(5) Consists of (i) 600,000 shares of common stock, (ii) 133,333 shares of common stock issuable upon the automatic conversion of 133,333 shares of Series A convertible preferred stock, (iii) shares of common stock issuable upon the automatic conversion of 53,334 shares of Series A-1 convertible preferred stock, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, (iv) 459 shares of common stock that represent accrued dividends on such Series A-1 convertible preferred stock, assuming that the closing occurred on December 1, 2013, (v) 1,600,000 shares of common stock issuable upon the exercise of stock options within 60 days of December 1, 2013 and (vi) 46,666 shares of common stock issuable upon the exercise of stock warrants within 60 days of December 1, 2013.

(6) Consists of 750,000 shares of common stock.

(7) Consists of (i) 5,530,000 shares of common stock, (ii) 133,333 shares of common stock issuable upon the automatic conversion of 133,333 shares of Series A convertible preferred stock and 4,077,475 shares of Series A convertible preferred stock held by Daniel Blech Trust DTD 8/3/2005, or the Blech Trust, (iii) 500,000 shares of common stock issuable upon the exercise of stock options within 60 days of December 1, 2013 and (iv) 33,333 shares of common stock issuable upon the exercise of warrants within 60 days of December 1, 2013, and 1,019,369 shares of common stock

issuable upon the exercise of warrants within 60 days of December 1, 2013 held by the Blech Trust. Mr. Blech disclaims beneficial ownership of the shares held by the Blech Trust.

(8) Consists of (i) 500,000 shares of common stock and (ii) 400,000 shares of common stock issuable upon the automatic conversion of 400,000 shares of Series A convertible preferred stock held by United Acquisition Corp., or United, which is indirectly 100% owned and controlled by Mr. Catsimatidis and (iii) 100,000 shares of common stock issuable upon the exercise of warrants within 60 days of December 1, 2013 held by United.

(9) Consists of (i) 500,000 shares of common, and (ii) 66,667 shares of common stock issuable upon the exercise of stock options within 60 days December 1, 2013.

(10) Consists of the number of shares beneficially owned by the directors and named executive officers listed in the above table, as well as (i) 245,001 shares of common stock issuable upon the exercise of stock options within 60 days of December 1, 2013 held by Dr. Mazhari, and (ii) 233,333 shares of common stock issuable upon the exercise of stock options within 60 days of December 1, 2013 held by Dr. Rowland.

DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of shares of common stock, par value $0.001 per share, and shares of convertible preferred stock, par value $0.001 per share. The following is a summary of the rights of our common and convertible preferred stock and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

Common Stock

On September 30, 2013, there were 18,000,000 shares of our common stock outstanding, held of record by 24 stockholders, 10,687,375 shares of our common stock subject to outstanding options and 14,258,810 shares of our common stock issuable upon the exercise of warrants outstanding as of September 30, 2013 at a weighted-average exercise price of $0.94 per share. Based on (i) 18,000,000 shares of our common stock outstanding as of September 30, 2013, (ii) the automatic conversion of all outstanding shares of our convertible preferred stock, including shares of common stock issuable as payment of accrued dividends, into an aggregate of shares of our common stock upon the closing of this offering assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and assuming that the closing occurred on and (iii) the issuance of shares of common stock in this offering, there will be shares of our common stock outstanding upon the closing of this offering.

Voting

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

Subject to preferences that may be applicable to any then outstanding convertible preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of convertible preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our convertible preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred Stock

On September 30, 2013, there were 31,116,391 shares of Series A convertible preferred stock outstanding, held of record by 154 stockholders, 9,074,511 shares of Series A-1 convertible preferred stock outstanding, held of record by 146 stockholders and an additional 31,000,000 shares of "blank check" preferred stock which may be issued from time to time by our board of directors in one or more series with such rights, preferences and privileges as determined by our board of directors. Pursuant to the terms of the convertible preferred stock, each share of Series A convertible preferred stock will automatically convert into shares of our common stock immediately prior to the closing of this offering, at a conversion price that is equal to $0.75 per share, and each share of Series A-1 convertible preferred stock will automatically convert into shares of our common stock immediately prior to the closing of this offering at a conversion price that is the lesser of (i) the initial public offering price per share of common stock in this offering multiplied by 75% and (ii) $0.75. Based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, each share of our Series A convertible preferred stock is convertible into approximately shares of our common stock and each share of our Series A-1 convertible preferred stock, together with shares of common stock issuable as payment of accrued dividends thereon, is convertible into approximately shares of our common stock, assuming that the closing occurred on . Accordingly, immediately upon the closing of this offering, the outstanding shares of convertible preferred stock will automatically convert into an aggregate amount of shares of our common stock.

Following this offering, under our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power, impair the liquidation rights of our common stock or otherwise adversely affect the rights of holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Options

As of September 30, 2013, options to purchase an aggregate of 10,687,375 shares of our common stock at a weighted-average exercise price of $0.28 per share were outstanding.

Warrants

The following table summarizes the warrants to purchase shares of our common stock outstanding as of September 30, 2013:

Number of Warrants	Number of Holders	Per Share Exercise Price	Expiration Date
2,210,290	43	$ 1.00	February 2017
819,776	36	$ 0.50	February 2017
3,405,035	45	$ 1.00	March 2017
827,990	33	$ 0.50	March 2017
3,646,559	2	$ 1.00	April 2017
400,000	3	$ 1.00	July 2017
2,949,160	150	$ 1.00	August 2018

Each of these warrants has a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of stock dividends, stock splits and reclassifications, consolidations or combinations.

The holders of certain of these warrants are entitled to registration rights under our Amended and Restated Investors' Rights Agreement, as described in more detail under " — Registration Rights."

Registration Rights

Under our Amended and Restated Investors' Rights Agreement, holders of 54,449,713 shares of our convertible preferred stock and warrants exercisable into 54,449,713 shares of our common stock have certain registration right with regard to the shares of common stock issuable upon the conversion of the convertible preferred stock or the exercise of warrants. The registration rights are described below.

Demand Registration Rights

At any time after 180 days after the closing of this offering, the holders of a majority of the shares then outstanding having demand registration rights may request that we register all or a portion of their shares of common stock for sale under the Securities Act. We will effect the registration as requested, unless, in the good faith judgment of our board of directors, such registration would be materially detrimental to the company and its stockholders and should be delayed. We are not obligated to file a registration statement pursuant to this provision on more than once.

In addition, when we are eligible for the use of Form S-3, or any successor form, holders of at least 20% of the shares then outstanding having demand registration rights may make requests that we register all or a portion of their common stock for sale under the Securities Act on Form S-3, or any successor form, so long as the aggregate price to the public in connection with any such offering is at least $5 million. We are not obligated to file a Form S-3 pursuant to this provision on more than two occasions in any 12-month period.

Incidental Registration Rights

In addition, if at any time after this offering we register any shares of our common stock for public sale, the holders of all shares having piggyback registration rights are entitled to notice of the registration and to include all or a portion of their shares of common stock in the registration.

Other Provisions

In the event that any registration in which the holders of registrable shares participate pursuant to the Amended and Restated Investors' Rights Agreement is an underwritten public offering, the number of registrable shares to be included may, in specified circumstances, be limited due to market conditions.

We will pay all registration expenses, other than underwriting discounts and selling commissions, and the reasonable fees and expenses of a single special counsel for the selling stockholders, related to any demand, piggyback and Form S-3 registration. The Amended and Restated Investors Rights Agreement contains customary cross-indemnification provisions, pursuant to which we must indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us, and they must indemnify us for material misstatements or omissions in the registration statement attributable to them. The demand, piggyback and Form S-3 registration rights described above will expire upon the earlier of (i) August 23, 2020, (ii) the holders may sell all registrable securities pursuant to Rule 144 without restrictions during any three-months period or (iii) the closing of a Deemed Liquidation Event, as such term is defined in our amended and restated certificate of incorporation as in effect prior to the closing of this offering.

Anti-Takeover Effects of Delaware Law and Our Charter and Bylaws

Provisions of Delaware law and our certificate of incorporation and by-laws could make it more difficult to acquire us by means of a tender offer, a proxy contest, open market purchases, removal of incumbent directors and otherwise. These provisions, summarized below, are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/_{3}\%$ of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

The existence of this provision generally will have an anti-takeover effect for transactions not approved in advance by the board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least $66^{2}/_{3}\%$ of our then outstanding common stock.

NASDAQ Capital Market Listing

We plan to apply to have our common stock our common stock listed on the NASDAQ Capital Market under the symbol "CERC."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is . The transfer agent and registrar's address is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market for our common stock existed, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options and warrants, or the anticipation of such sales, could adversely affect prevailing market prices of our common stock from time to time and could impair our ability to raise equity capital in the future. Furthermore, because only a limited number of shares of our common stock will be available for sale shortly after this offering due to certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after such restrictions lapse, or the anticipation of such sales, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future. We plan to apply to have our common stock listed on the NASDAQ Capital Market under the symbol "CERC."

Upon the closing of this offering, we will have outstanding shares of our common stock, after giving effect to the issuance of shares of our common stock in this offering and the automatic conversion of all outstanding shares of our convertible preferred stock, including shares of common stock issuable as payment of accrued dividends, into an aggregate of shares of our common stock upon the closing of this offering assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and assuming that the closing occurred on . The number of shares outstanding upon the closing of this offering assumes no exercise of outstanding options or warrants.

All of the shares sold in this offering will be freely tradable unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. The remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements as described below. Following the expiration of the lock-up period, all shares will be eligible for resale, subject to compliance with Rule 144 or Rule 701 of the Securities Act, to the extent these shares have been released from any repurchase option that we may hold.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, shares of common stock that are either subject to outstanding options or warrants or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 of the Securities Act.

Rule 144

In general, under Rule 144 of the Securities Act, as in effect on the date of this prospectus, beginning 90 days after the date of this prospectus, any person who is not our affiliate at any time during the preceding three months, and who has beneficially owned their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares of our common stock provided current public information about us is available, and, after owning such shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares of our common stock without restriction.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months, and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our

affiliates, is entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares, or shares if the underwriters exercise their over-allotment option in full, immediately following this offering, based on the number of shares of our common stock outstanding upon the closing of this offering; or

- the average weekly trading volume of our common stock on NASDAQ during the four calendar weeks preceding the filing of a Notice of Proposed Sale of Securities pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon expiration of the 180-day lock-up period described below, shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act, is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

Lock-up Agreements

As described under the section entitled "Underwriting — Lock-Up Agreements" below, we, each of our directors and officers, the holders of substantially all of the other shares of our common stock outstanding prior to this offering and the holders of substantially all of our options outstanding prior to this offering, have agreed, subject to specified exceptions, not to, directly or indirectly, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock or (ii) enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock, without the prior written consent of Wells Fargo Securities, LLC and JMP Securities LLC, for a period of 180 days following the date of this prospectus for the offering.

Wells Fargo Securities, LLC and JMP Securities LLC, may, in their sole discretion, at any time or from time to time and without notice, release for sale in the public market all or any portion of the shares restricted by the terms of the lock-up agreements.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding stock options and common stock issuable under our equity incentive plans. We expect to file the registration statement covering such shares shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public

market, subject to compliance with the resale provisions of Rule 144. For more information on our equity incentive plans, see "Executive Compensation — Stock Incentive Plans."

Registration Rights

Holders of 54,449,713 shares of our convertible preferred stock and warrants exercisable into 54,449,713 shares of our common stock have the right to demand that we file a registration statement or request that we cover their shares by a registration statement that we otherwise file. For more information, see "Description of Capital Stock — Registration Rights." Except for shares purchased by affiliates, registration of their shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement, subject to the expiration of the lock-up period and to the extent these shares have been released from any repurchase option that we may hold.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a general discussion of material U.S. federal income tax considerations relating to ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, the term "non-U.S. holder" means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or if the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury regulations.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. In addition, the Internal Revenue Service, or the IRS, could challenge one or more of the tax consequences described in this prospectus.

We assume in this discussion that each non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. federal estate or gift taxes, and state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other entities which are pass-through entities for U.S.

federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other pass-through entity, as applicable.

Prospective investors should consult their tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock.

Dividends

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we make distributions of cash or property on our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "Gain on Disposition of Common Stock."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements by providing a properly executed IRS Form W-8ECI (or successor form). However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the regular graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Gain on Disposition of Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax on gain realized on a disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated

rates and in the manner applicable to U.S. persons, and, if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

- the non-U.S. holder is a non-resident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder, if any; or

- we are or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation." Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. Even if we are or were to become a U.S. real property holding corporation, gains realized by a non-U.S. holder on a disposition of our common stock will not be subject to U.S. federal income tax if our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the non-U.S. holder's holding period. No assurance can be provided that our common stock will continue to be regularly traded on an established securities market for purposes of the rule described above.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder payments of dividends on our common stock to such holder and the tax withheld, if any, with respect to such dividends. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 28%, with respect to dividends on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under " — Dividends," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Recently-Enacted Legislation Relating to Foreign Accounts

Legislation enacted in March 2010, commonly referred to as FATCA, generally will impose a 30% withholding tax on dividends of, and gross proceeds from the sale or disposition, of our common stock if paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) the non-financial foreign entity identifies its "substantial United States owner" (as defined in the Code) or certifies that it does not have any substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity is otherwise exempt under FATCA.

Pursuant to final regulations issued by the U.S. Department of Treasury and recently issued guidance, withholding under FATCA will only apply (i) to payments of dividends on our common stock made after June 30, 2014 and (ii) to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2016. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of the tax. Non-U.S. holders should consult their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

The preceding discussion of material U.S. federal tax considerations is for general information only. It is not tax advice. Prospective investors should consult their tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement, we have agreed to sell to the underwriters named below, and the underwriters, for whom Wells Fargo Securities, LLC and JMP Securities LLC are acting as joint book running manager and representatives, have severally agreed to purchase, the respective numbers of shares of common stock appearing opposite their names below:

Underwriter	Number of Shares
Wells Fargo Securities, LLC	
JMP Securities LLC	
Needham & Company, LLC	
Total	

All of the shares to be purchased by the underwriters will be purchased from us.

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions, including approval of legal matters by counsel. The shares of common stock are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them. The underwriters reserve the right to withdraw, cancel or modify the offer and to reject orders in whole or in part.

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock offered by this prospectus if any are purchased, other than those shares covered by the over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

Over-Allotment Option

We have granted a 30-day option to the underwriters to purchase up to a total of additional shares of our common stock from us at the initial public offering price per share less the underwriting discounts and commissions per share, as set forth on the cover page of this prospectus, and less any dividends or distributions declared, paid or payable on the shares that the underwriters have agreed to purchase from us but that are not payable on such additional shares, to cover over-allotment, if any. If the underwriters exercise this option in whole or in part, then the underwriters will be severally committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of our common stock in proportion to their respective commitments set forth in the prior table.

Discounts and Commissions

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession of not more than $ per share, of which up to $ per share may be reallowed to other dealers. After the initial offering, the public offering price, concession and reallowance to dealers may be changed.

The following table summarizes the underwriting discounts and commissions and the proceeds, before expenses, payable to us, both on a per share basis and in total, assuming either no exercise or full exercise by the underwriters of their over-allotment option:

		Total	
	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discounts and commissions	$	$	$
Proceeds, before expenses, to us	$	$	$

We estimate that the expenses of this offering payable by us, not including underwriting discounts and commissions, will be approximately $ million. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to $ as set forth in the underwriting agreement.

Indemnification of Underwriters

The underwriting agreement provides that we will indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in respect of those liabilities.

Lock-Up Agreements

We, each of our directors and officers, the holders of substantially all of the other shares of our common stock outstanding prior to this offering and the holders of substantially all of our options outstanding prior to this offering, have agreed, subject to specified exceptions, that, without the prior written consent of Wells Fargo Securities, LLC, and JMP Securities LLC, we and they will not, during the period beginning on and including the date of this prospectus through and including the date that is the 180th day after the date of this prospectus, directly or indirectly:

- issue (in the case of us), offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock;

- in the case of us, file or cause the filing of any registration statement under the Securities Act with respect to any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock, other than registration statements on Form S-8 filed with the SEC after the closing date of this offering; or

- enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock,

whether any transaction described in any of the foregoing bullet points is to be settled by delivery of our common stock or other capital stock, other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing.

Wells Fargo Securities, LLC and JMP Securities LLC may, in their sole discretion and at any time or from time to time, without notice, release all or any portion of the shares or other securities subject to the lock-up agreements. Any determination to release any shares or other securities subject to the lock- up agreements would be based on a number of factors at the time of determination, which may include

the market price of the common stock, the liquidity of the trading market for the common stock, general market conditions, the number of shares or other securities proposed to be sold or otherwise transferred and the timing, purpose and terms of the proposed sale or other transfer.

NASDAQ Capital Market Listing

We plan to apply to have our common stock our common stock listed on the NASDAQ Capital Market under the symbol "CERC."

Stabilization

In order to facilitate this offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the market price of our common stock. Specifically, the underwriters may sell more shares of common stock than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares of common stock available for purchase by the underwriters under the over-allotment option. The underwriters may close out a covered short sale by exercising the over-allotment option or purchasing common stock in the open market. In determining the source of common stock to close out a covered short sale, the underwriters may consider, among other things, the market price of common stock compared to the price payable under the over-allotment option. The underwriters may also sell shares of common stock in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after the date of pricing of this offering that could adversely affect investors who purchase in this offering.

As an additional means of facilitating this offering, the underwriters may bid for, and purchase, common stock in the open market to stabilize the price of our common stock, so long as stabilizing bids do not exceed a specified maximum. The underwriting syndicate may also reclaim selling concessions allowed to an underwriter or a dealer for distributing common stock in this offering if the underwriting syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the common stock.

The foregoing transactions, if commenced, may raise or maintain the market price of our common stock above independent market levels or prevent or retard a decline in the market price of the common stock.

The foregoing transactions, if commenced, may be effected on the NASDAQ Capital Market or otherwise. Neither we nor any of the underwriters makes any representation that the underwriters will engage in any of these transactions and these transactions, if commenced, may be discontinued at any time without notice. Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of the effect that the transactions described above, if commenced, may have on the market price of our common stock.

Discretionary Accounts

The underwriters have informed us that they do not intend to confirm sales to accounts over which they exercise discretionary authority in excess of five percent of the total number of shares of common stock offered by them.

Pricing of this Offering

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price for our common stock was determined between us and the representatives of the underwriters. The factors considered in determining the initial public offering price included:

- prevailing market conditions;
- our results of operations and financial condition;
- financial and operating information and market valuations with respect to other companies that we and the representatives of the underwriters believe to be comparable or similar to us;
- the present state of our development; and
- our future prospects.

An active trading market for our common stock may not develop. It is possible that the market price of our common stock after this offering will be less than the initial public offering price.

Relationships

The underwriters and their respective affiliates are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed various commercial banking and brokerage activities for us, for which they received customary fees and commissions. The underwriters and their respective affiliates may in the future perform these and other financial advisory and investment banking services for us, for which they will receive customary fees and commissions.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of instruments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve our securities and/or instruments. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Sales Outside the United States

No action has been taken in any jurisdiction (except in the United States) that would permit an initial public offering of the shares of our common stock that are the subject of the offering contemplated by this prospectus, or the possession, circulation or distribution of this prospectus or any other material relating to us or the shares in any jurisdiction where action for that purpose is required. Accordingly, the shares may not be offered or sold, directly or indirectly, and none of this prospectus or any other offering material or advertisements in connection with the shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction.

Each of the underwriters may arrange to sell shares offered hereby in certain jurisdictions outside the United States, either directly or through affiliates, where they are permitted to do so. In that regard, Wells Fargo Securities, LLC may arrange to sell shares in certain jurisdictions through an affiliate, Wells Fargo Securities International Limited, or WFSIL. WFSIL is a wholly-owned indirect subsidiary of Wells Fargo & Company and an affiliate of Wells Fargo Securities, LLC. WFSIL is a U.K. incorporated investment firm regulated by the Financial Services Authority. Wells Fargo Securities is the trade name

for certain corporate and investment banking services of Wells Fargo & Company and its affiliates, including Wells Fargo Securities, LLC and WFSIL.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), including each Relevant Member State that has implemented amendments to Article 3(2) of the Prospectus Directive introduced by the 2010 PD amending Directive (each, an "Early Implementing Member State"), an offer of the shares to the may not be made in that Relevant Member State and each underwriter represents and agrees that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the "Relevant Implementation Date") it has not made and will not make an offer of the shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that an offer of the shares to the public in that Relevant Member State may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(i) to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;

(ii) to fewer than 100 (or, in the case of Early Implementing Member States, 150) natural or legal persons (other than "qualified investors" as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives of the underwriters; or

(iii) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of the shares referred to in (a) to (c) above shall require the company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, warranted and agreed to and with the company or any underwriter that it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe to the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71 EC of the European Parliament and of the Council of 4 November 2003 (and amendments thereto, including the 2010 PD Amending Directive to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State. The expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

This prospectus and any other material in relation to the shares described herein is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2 (1) (e) of the Prospective Directive that also (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order"), (ii) fall within Article 49(2)(a) to (d) of the Order and (iii) are persons to whom it may otherwise lawfully be communicated (all such persons together being referred to as "relevant persons"). The shares are only available to, and any invitation, offer or agreement to engage in investment activity with respect to such shares will be

engaged in only with, relevant persons. This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this prospectus or any of its contents.

The distribution of this prospectus in the United Kingdom to anyone not falling within the above categories is not permitted and may contravene the United Kingdom Financial Services and Markets Act 2000. No person falling outside those categories should treat this prospectus as constituting a promotion to him, or act on it for any purposes whatever. Recipients of this prospectus are advised that we, the underwriters and any other person that communicates this prospectus are not, as a result solely of communicating this prospectus, acting for or advising them and are not responsible for providing recipients of this prospectus with the protections which would be given to those who are clients of any aforementioned entities that is subject to the rules and regulations of the Financial Services Authority.

Notice to Prospective Investors in France

We and the underwriters have not offered or sold and will not offer or sell, directly or indirectly, shares to the public in France, and have not distributed or caused to be distributed and will not distribute or cause to be distributed to the public in France, this prospectus or any other offering material relating to the shares. Offers, sales and distributions that have been and will be made in France have been and will be made only to (a) providers of the investment service of portfolio management for the account of third parties, and (b) qualified investors (investisseurs qualifiés), other than individuals, all as defined in, and in accordance with, Articles L. 411-1, L. 411-2, and D. 411-1 of the French Code monétaire et financier.

Shares may be resold directly or indirectly only in compliance with Article L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the French Code monétaire et financier.

Neither this prospectus prepared in connection with the shares nor any other offering material relating to the shares has been submitted to the clearance procedures of the Autorité des marchés financiers or notified to the Autorité des marchés financiers by the competent authority of another member state of the European Economic Area.

Notice to Prospective Investors in Germany

The shares offered by this prospectus have not been and will not be offered to the public within the meaning of the German Securities Prospectus Act (Wertpapierprospektgesetz). No securities prospectus pursuant to the German Securities Prospectus Act has been or will be published or circulated in Germany or filed with the German Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht). This prospectus does not constitute an offer to the public in Germany, and it does not serve for public distribution of the shares in Germany. Neither this prospectus, nor any other document issued in connection with this offering, may be issued or distributed to any person in Germany except under circumstances that do not constitute an offer to the public under the German Securities Prospectus Act. Prospective Investors should consult with their legal and/or tax advisor before investing into the shares.

Notice to Prospective Investors in Ireland

This prospectus and any other material in relation to the shares described herein is only being distributed in Ireland:

(i) in circumstances which do not require the publication of a prospectus pursuant to Article 3(2) of Directive 2003/71/EC as amended by Directive 2010/73/EC;

(ii) in compliance with the provisions of the Irish Companies Acts 1963-2009; and

(iii) in compliance with the provisions of the European Communities (Markets in Financial Instruments) Regulations 2007 (S.I. No. 60 of 2007) (as amended), and in accordance with any codes or rules of conduct and any conditions or requirements, or any other enactment, imposed or approved by the Central Bank of Ireland with respect to anything done by them in relation to the shares.

Notice to Prospective Investors in Italy

The offering of the shares has not been registered pursuant to Italian securities legislation and, accordingly, no shares may be offered, sold or delivered, nor may copies of the prospectus or of any other document relating to the shares be distributed in the Republic of Italy, except:

(i) to qualified investors (investitori qualificati), as defined pursuant to Article 100 of Legislative Decree No. 58 of 24 February 1998, as amended (the Financial Services Act) and Article 34-ter, first paragraph, letter b) of CONSOB Regulation No. 11971 of 14 May 1999, as amended from time to time (Regulation No. 11971); or

(ii) in other circumstances which are exempted from the rules on public offerings pursuant to Article 100 of the Financial Services Act and Article 34-ter of Regulation No. 11971.

Any offer, sale or delivery of the shares or distribution of copies of the prospectus or any other document relating to the shares in the Republic of Italy under (i) or (ii) above must be:

(a) made by an investment firm, bank or financial intermediary permitted to conduct such activities in the Republic of Italy in accordance with the Financial Services Act, CONSOB Regulation No. 16190 of 29 October 2007 (as amended from time to time) and Legislative Decree No. 385 of 1 September 1993, as amended (the Banking Act); and

(b) in compliance with Article 129 of the Banking Act, as amended, and the implementing guidelines of the Bank of Italy, as amended from time to time, pursuant to which the Bank of Italy may request information on the issue or the offer of shares in the Republic of Italy; and

(c) in compliance with any other applicable laws and regulations or requirement imposed by CONSOB or other Italian authority. Please note that in accordance with Article 100-bis of the Financial Services Act, where no exemption from the rules on public offerings applies under (i) and (ii) above, the subsequent distribution of the shares on the secondary market in Italy must be made in compliance with the public offer and the prospectus requirement rules provided under the Financial Services Act and Regulation No. 11971. Failure to comply with such rules may result in the sale of such shares being declared null and void and in the liability of the intermediary transferring the shares for any damages suffered by the investors.

Notice to Prospective Investors in the Netherlands

The shares will not be offered or sold, directly or indirectly, in the Netherlands, other than:

(i) with a minimum denomination of €50,000 or the equivalent in another currency per investor;

(ii) for a minimum consideration of €50,000 or the equivalent in another currency per investor;

(iii) to fewer than 100 individuals or legal entities other than 'Qualified Investors' (see below); or

(iv) solely to Qualified Investors, all within the meaning of Article 4 of the Financial Supervision Act Exemption Regulation (Vrijstellingsregeling Wet op het financieel toezicht) and Article 1:12 and Article 5:3 of the Financial Supervision Act (Wet op het financieel toezicht, FSA).

Notice to Prospective Investors in Switzerland

This document as well as any other material relating to the shares of our common stock that are the subject of the offering contemplated by this prospectus do not constitute an issue prospectus pursuant to Article 652a or Article 1156 of the Swiss Code of Obligations. Our common stock will not be listed on the SWX Swiss Exchange and, therefore, the documents relating to our common stock, including, but not limited to, this document, do not claim to comply with the disclosure standards of the listing rules of SWX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SWX Swiss Exchange.

Our common stock is being offered in Switzerland by way of a private placement, i.e., to a small number of selected investors only, without any public offer and only to investors who do not purchase shares of our common stock with the intention to distribute them to the public. The investors will be individually approached by us from time to time.

This document as well as any other material relating to our common stock is personal and confidential and does not constitute an offer to any other person. This document may only be used by those investors to whom it has been handed out in connection with the offering described herein and may neither directly nor indirectly be distributed or made available to other persons without our express consent. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in (or from) Switzerland.

LEGAL MATTERS

The validity of the shares of common stock offered hereby is being passed upon for us by Morgan, Lewis & Bockius LLP, Philadelphia, Pennsylvania. The underwriters are being represented by Latham & Watkins LLP, San Diego, California.

EXPERTS

The financial statements of Cerecor Inc. at December 31, 2012 and 2011, and for the period from January 31, 2011 (inception) to December 31, 2011, the year ended December 31, 2012 and for the period from January 31, 2011 (inception) to December 31, 2012, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 400 E Pratt Street, Suite 606, Baltimore, Maryland 21202 or telephoning us at (410) 522-8707.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.cerecor.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website incorporated by reference in, and is not part of, this prospectus.

CERECOR INC.
(A Development Stage Entity)

Index to Financial Statements

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. (a Development Stage Entity) (the "Company") as of December 31, 2012 and 2011, and the related statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for the period from January 31, 2011 (inception) to December 31, 2011, the year ended December 31, 2012 and the period from January 31, 2011 (inception) to December 31, 2012. 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, 2012 and 2011, and the results of its operations and its cash flows for the period from January 31, 2011 (inception) to December 31, 2011, the year ended December 31, 2012 and the period from January 31, 2011 (inception) to December 31, 2012, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Baltimore, Maryland
December 20, 2013

CERECOR INC.
(A Development Stage Entity)

Balance Sheets

	December 31, 2011	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 1,111,200	$ 9,519,661
Prepaid expenses and other current assets	113,479	429,965
Total current assets	1,224,679	9,949,626
Property and equipment, net	59,323	56,752
Other assets	2,248	13,310
Total assets	$ 1,286,250	$ 10,019,688
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Due to related party	$ 100,000	$ —
Convertible demand promissory note — due to related party	3,037,099	—
Accounts payable	241,747	821,114
Accrued expenses and other current liabilities	314,494	722,680
Deferred revenue	82,760	—
Total current liabilities	3,776,100	1,543,794
Convertible preferred stock:		
Series A — $0.001 par value; 0 and 43,000,000 shares authorized at December 31, 2011 and 2012, respectively, 0 and 31,116,391 shares issued and outstanding at December 31, 2011 and 2012, respectively (aggregate liquidation preference of $0 and $23,337,293 at December 31, 2011 and 2012, respectively)	—	19,856,632
Total convertible preferred stock	—	19,856,632
Stockholders' deficit:		
Common Stock — $0.001 par value, 20,000,000 and 87,000,000 shares authorized at December 31, 2011 and 2012, respectively, 18,000,000 shares issued and outstanding at December 31, 2011 and 2012	18,000	18,000
Additional paid-in capital	975,329	2,574,040
Deficit accumulated during the development stage	(3,483,179)	(13,972,778)
Total stockholders' deficit	(2,489,850)	(11,380,738)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 1,286,250	$ 10,019,688

See accompanying notes to financial statements.

CERECOR INC.
(A Development Stage Entity)

Statements of Operations

	Period From January 31, 2011 (Inception) to December 31, 2011	Year Ended December 31, 2012	Period From January 31, 2011 (Inception) to December 31, 2012
Grant revenue	$ 209,716	$ 82,760	$ 292,476
Operating expenses:			
Research and development	2,818,096	8,476,604	11,294,700
General and administrative	838,056	2,097,105	2,935,161
Total operating expenses	3,656,152	10,573,709	14,229,861
Loss from operations	(3,446,436)	(10,490,949)	(13,937,385)
Other income (expense):			
Interest expense	(37,099)	(21,007)	(58,106)
Interest income	356	22,357	22,713
Total other income (expense)	(36,743)	1,350	(35,393)
Net loss	$ (3,483,179)	$ (10,489,599)	$ (13,972,778)
Net loss per share, basic and diluted	$ (0.29)	$ (0.59)	
Weighted-average shares outstanding, basic and diluted	11,900,895	17,642,964	
Pro forma net loss per share, basic and diluted (unaudited)		$	
Pro forma net loss per share, basic and diluted weighted-average shares outstanding (unaudited)			

See accompanying notes to financial statements.

CERECOR INC.
(A Development Stage Entity)

Statements of Convertible Preferred Stock and Stockholders' Deficit

For the Period From January 31, 2011 (Inception) to December 31, 2012

	Convertible Preferred Stock — Series A		Stockholders' Deficit				
			Common Stock				
	Number of Shares	Amount	Number of Shares	Par Value	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
Balance, January 31, 2011 (Inception)	—	$ —	—	$ —	$ —	$ —	$ —
Issuance of Common Stock	—	—	18,000,000	18,000	—	—	18,000
Stock-based compensation expense	—	—	—	—	975,329	—	975,329
Net loss	—	—	—	—	—	(3,483,179)	(3,483,179)
Balance, December 31, 2011	—	—	18,000,000	18,000	975,329	(3,483,179)	(2,489,850)
Issuance of Series A convertible preferred stock, net of issuance costs	31,116,391	19,856,632	—	—	—	—	—
Issuance of Common Stock warrants	—	—	—	—	1,010,582	—	1,010,582
Stock-based compensation expense	—	—	—	—	588,129	—	588,129
Net loss	—	—	—	—	—	(10,489,599)	(10,489,599)
Balance, December 31, 2012	31,116,391	$ 19,856,632	18,000,000	$ 18,000	$ 2,574,040	$ (13,972,778)	$ (11,380,738)

See accompanying notes to financial statements.

CERECOR INC.
(A Development Stage Entity)

Statements of Cash Flows

	Period From January 31, 2011 (Inception) to December 31, 2011	Year Ended December 31, 2012	Period From January 31, 2011 (Inception) to December 31, 2012
Operating activities			
Net loss	$ (3,483,179)	$ (10,489,599)	$ (13,972,778)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,104	15,003	17,107
Stock-based compensation expense	975,329	588,129	1,563,458
Non-cash interest expense	37,099	21,007	58,106
Changes in assets and liabilities:			
Prepaid expenses and other assets	(115,727)	(327,549)	(443,276)
Accrued liabilities and employee benefits	414,494	408,187	822,681
Accounts payable	241,747	579,367	821,114
Deferred revenue	82,760	(82,760)	—
Net cash used in operating activities	(1,845,373)	(9,288,215)	(11,133,588)
Investing activities			
Purchase of property and equipment	(61,427)	(12,432)	(73,859)
Net cash used in investing activities	(61,427)	(12,432)	(73,859)
Financing activities			
Proceeds from issuance of convertible promissory note	3,000,000	—	3,000,000
Proceeds from issuance of Common Stock	18,000	—	18,000
Proceeds from issuance of Series A Convertible Preferred Stock, and Common Stock warrants, net of offering costs	—	17,709,108	17,709,108
Net cash provided by financing activities	3,018,000	17,709,108	20,727,108
Increase in cash and cash equivalents	1,111,200	8,408,461	9,519,661
Cash and cash equivalents at beginning of period	—	1,111,200	—
Cash and cash equivalents at end of period	$ 1,111,200	$ 9,519,661	$ 9,519,661
Supplemental disclosures of cash flow information			
Due to related party converted to Series A Convertible Preferred Stock and Common Stock warrants	$ —	$ 100,000	$ 100,000
Convertible demand promissory note — due to related party converted to Series A Convertible Preferred Stock and Common Stock warrants	$ —	$ 3,058,106	$ 3,058,106

See accompanying notes to financial statements.

CERECOR INC.
(A Development Stage Entity)

Notes to Financial Statements

December 31, 2012

1. BUSINESS

Description of Business and Organization

Cerecor Inc. (the "Company" or "Cerecor") was incorporated on January 31, 2011 in Delaware as Ceregen Corporation and subsequently changed the name to Cerecor Inc. in March 2011. The Company is a clinical-stage biopharmaceutical company committed to becoming a leader in the development and commercialization of innovative drugs that address the needs of underserved patients with nervous system disorders. The Company's operations since inception have been limited to organizing and staffing the Company, acquiring rights to and developing certain product candidates and its product platform, business planning and raising capital. Accordingly, the Company is considered to be in the development stage as defined by Accounting Standards Codification ("ASC") 915, *Development Stage Entities* ("ASC 915"). The Company's principal office is in Baltimore, Maryland. The Company's revenue to date has been derived solely from research grants.

Liquidity

The Company has incurred recurring operating losses since inception. For the year ended December 31, 2012, the Company incurred a net loss of $10,489,599 and as of December 31, 2012, the Company had generated an accumulated deficit of $13,972,778. The Company has not generated any product revenue to date. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to the clinical development of its product candidates, its product platform, its preclinical programs, business development and the development of its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy. To fully execute its business plan, the Company will need to complete certain research and development activities, clinical trials and obtain marketing approval for its product candidates, which may span many years, and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company plans to meet its capital requirements primarily through a combination of equity and debt financings, collaborations, strategic alliances and marketing distribution or licensing arrangements and in the longer term, revenue from product sales to the extent its product candidates receive marketing approval and are commercialized. There can be no assurance, however, that the Company will be successful in obtaining financing at the level needed to sustain operations or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow. The Company currently anticipates that its cash and cash equivalents will be sufficient to meet its anticipated cash requirements through the first quarter of 2014.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements have been prepared in conformity with U. S. generally accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

CERECOR INC.
(A Development Stage Entity)

Notes to Financial Statements — (Continued)

December 31, 2012

Unaudited Pro Forma Presentation

On December 17, 2013, the Company's Board of Directors authorized management of the Company to confidentially submit a registration statement to the Securities and Exchange Commission (the "SEC") for the Company to sell shares of its Common Stock (the "Common Stock") to the public. The unaudited pro forma net loss per share is computed using the weighted-average number of shares of Common Stock outstanding and gives effect to the automatic conversion of all outstanding shares of the Company's Series A Convertible Preferred Stock into an aggregate of 31,116,391 shares of the Company's Common Stock, as if it had occurred on January 1, 2012 or the date of original issuance, if later.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, other comprehensive income and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to clinical trial accruals. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

In addition, the Company utilizes estimates and assumptions in determining the fair value of its Common Stock. The Company granted stock options at exercise prices not less than the fair value of its Common Stock as determined by the Board of Directors, with input from management. Management uses the assistance of a third-party valuation firm in estimating the fair value of the Common Stock. The Board of Directors has determined the estimated fair value of the Common Stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the historic prices at which the Company sold shares of its Series A Convertible Preferred Stock.

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.

Fair Value of Financial Instruments

The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, accounts payable and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts.

Based on the borrowing rates available to the Company for debt with similar terms and consideration of default and credit risk, as well as the short-term maturity (all Level 3 inputs as defined in Note 4), the carrying value of the convertible demand promissory note — due to related party approximates its fair value at December 31, 2011. The convertible demand promissory note — due to related party was converted to Series A Convertible Preferred Stock during 2012. No changes in valuation techniques or inputs occurred during the year ended December 31, 2012.

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

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December 31, 2012

balances in the form of money market accounts with financial institutions that management believes are creditworthy. The Company has no financial instruments with off-balance sheet risk of loss.

Property and Equipment

Property and equipment consists of computer, software, 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 office 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.

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the asset or asset group may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceeds their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded since inception.

Grant Revenue Recognition

The Company recognizes grant revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable, and collectability is reasonably assured. In August 2011, the Company received a research grant from the National Heart, Lung, and Blood Institute of the National Institute of Health to assist in the funding of certain research activities through July 2012. The amount of the award was $292,476, which was received in 2011. The Company has recognized revenue in the amounts of $209,716 and $82,760, for the period from January 31, 2011 (inception) to December 31, 2011 and for the year end December 31, 2012, respectively, and $292,476 from January 31, 2011 (inception) through December 31, 2012. The Company recognizes revenue under grants in earnings in the period in which the related expenditures are incurred. As the entire grant was received during 2011, but a certain portion of the research work was not completed until 2012, the Company recorded deferred revenue of $82,760 as of December 31, 2011.

Research and Development

Research and development costs are expensed as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits and stock-based compensation of our research and development personnel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; other supplies; facilities, depreciation 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

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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, 2012, the Company does not believe any material uncertain tax positions are present. Accordingly, interest and penalties have not been accrued due to an uncertain tax position and the fact the Company has reported tax losses since inception.

Stock-Based Compensation

At December 31, 2012, the Company had one stock-based compensation plan, which is more fully described in Note 10. The Company applies the provisions of ASC 718, *Compensation — Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including employee stock options in the statement of operations.

For stock options issued to employees and members of the Board of Directors for their services on the Board of Directors, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the Common Stock consistent with the expected life of the option, risk-free interest rates, the value of the Common Stock and expected dividend yields of the Common Stock. For awards subject to service-based

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vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock-based payments issued to non-employees are recorded at their grant date fair values, are revalued as the underlying equity instruments vest and are recognized as expense over the earlier of the period ending with the performance commitment date or the date the services are completed in accordance with the provisions of ASC 718 and ASC 505, *Equity* ("ASC 505"). See Note 10 for a discussion of the assumptions used by the Company in determining the grant date fair value of options granted under the Black-Scholes option pricing model, as well as a summary of the stock option activity under the Company's stock-based compensation plan.

Clinical Trial Expense Accruals

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the period from January 31, 2011 (inception) through December 31, 2011 and for the year ended December 31, 2012, 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.

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Recent Accounting Pronouncements

On April 5, 2012, the Jump-Start Our Business Startups Act (the "JOBS Act") was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." The Company is considered an emerging growth company, but has elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. As a result, the Company 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.

In June 2011, FASB issued ASU No. 2011-05, "Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income" ("ASU 2011-05"). This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of stockholders' equity. Instead, comprehensive income must be presented in either a single continuous statement of comprehensive income, which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 was effective for fiscal periods beginning after December 15, 2011, with early adoption permitted. The Company's retrospective adoption of ASU 2011-05 did not have a significant impact on its financial position, results of operations or cash flows.

In February 2013, FASB issued ASU No. 2013-02, "Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income" ("ASU 2013-02"). ASU 2013-02 requires companies to present either in a single note or parenthetically on the face of the financial statements, the effect of significant amounts reclassified from each component of accumulated other comprehensive income based on its source and the income statement line items affected by the reclassification. This guidance is effective for annual reporting periods beginning after December 15, 2012. The Company believes the adoption of this standard will not have a significant impact on its financial position, results of operations or cash flows.

3. NET LOSS PER COMMON SHARE

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Period from January 31, 2011 (Inception) to December 31, 2011	Year ended December 31, 2012
Basic and diluted net loss per common share calculation:		
Net loss	$ (3,483,179)	$ (10,489,599)
Weighted-average common shares outstanding	11,900,895	17,642,964
Net loss per share of common stock — basic and diluted	$ (0.29)	$ (0.59)

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The following outstanding securities at December, 31, 2011 and 2012 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	December 31, 2011	December 31, 2012
Series A Convertible Preferred Stock	—	31,116,391
Unvested restricted stock	400,000	300,000
Stock options	475,000	9,300,000
Warrants	—	11,309,649
Total	875,000	52,026,040

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.

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 at December 31, 2011.

	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*	$ 514,995	$ —	$ —

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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 at December 31, 2012.

	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*	$ 9,440,841	$ —	$ —

* Investments in money market funds are reflected in cash and cash equivalents in the accompanying Balance Sheets.

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31,	
	2011	2012
Furniture	$ 53,903	$ 57,923
Computers and software	7,524	15,936
Total property and equipment	61,427	73,859
Less accumulated depreciation	(2,104)	(17,107)
Property and equipment, net	$ 59,323	$ 56,752

Depreciation and amortization expense was $2,000 and $15,000 for the period from January 31, 2011 (inception) to December 31, 2011 and the year ended December 31, 2012, respectively, and $17,000 for the period from January 31, 2011 (inception) to December 31, 2012.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2011	2012
Compensation and benefits	$ 125,000	$ 336,185
Research and development expenses	168,750	372,017
Other	20,744	14,478
Total accrued expenses and other current liabilities	$ 314,494	$ 722,680

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7. ASSET ACQUISITION AND LICENSE AGREEMENTS

In May 2011, the Company entered into an asset purchase agreement with Fells Laboratories LLC ("Fells") for the acquisition of certain assets owned or licensed by Fells, all related to a compound known as FP01. The Company also assumed certain contractual obligations relating to FP01. The principal assets acquired consisted of three patents owned by Fells and a license with Johns Hopkins University ("JHU"), which includes rights to two additional patents. According to the terms of the Agreement, the Company paid $540,000, which consisted of a $340,000 upfront payment in May 2011, which was expensed as research and development during the period from January 31, 2011 (inception) to December 31, 2011 and a $200,000 milestone payment in July 2012, which was expensed as research and development during the year ended December 31, 2012, upon the successful completion of the prototype of the formulation of FP01. The Company could be required to pay up to an additional $2.9 million to Fells upon the achievement of certain contingent development and regulatory milestones.

The Company accounted for this transaction as an asset acquisition because it only acquired the assigned rights and technology and did not acquire any processes or activities. The majority shareholder of Fells is the Company's President and Chief Executive Officer.

Pursuant to the terms of the license agreement between JHU and Fells, which the Company assumed in the acquisition, the Company may be required to make contingent milestone payments to JHU of up to $375,000 upon the achievement of certain development and regulatory milestones. During 2012, the Company paid JHU $5,000, which has been recorded as research and development expenses in the accompanying statement of operations. The Company is not currently developing FP01 and does not expect to pay any additional fees to Fells or JHU unless the Company out-licenses FP01 to a third party for development.

8. DEBT

Convertible Demand Promissory Note — Due to Related Party

On April 29, 2011, the Company executed a convertible demand promissory note with an affiliate of a member of the Company's Board of Directors. Under this note, advances were made to the Company in April through November 2011 for an aggregate principal amount of $3,000,000. The convertible demand promissory note carried a 3% annual interest rate compounded quarterly on the unpaid principal amount. All principal and accrued interest was payable on demand. The convertible demand promissory note provided for the automatic conversion of the outstanding principal and unpaid interest upon the completion of an equity offering that generated aggregate net proceeds in excess of $10,000,000 ("Equity Offering"). In the event of this conversion, the convertible demand promissory note would automatically convert into equity instruments equivalent to those issued in the Equity Offering at a conversion price equal to lowest price per share paid by other investors and at the same terms and conditions as the other investors.

The initial terms of the convertible demand promissory note called for an automatic conversion into shares of Common Stock at a price per share of $1.00, at December 31, 2011, if an Equity Offering had not occurred. In December 2011, the date for the automatic conversion of the convertible demand promissory note into shares of Common Stock was extended to June 30, 2012. On March 23, 2012, pursuant to the terms for automatic conversion upon an Equity Offering, the outstanding principal and unpaid interest converted into shares of Series A Convertible Preferred Stock. Upon conversion the holder received 4,077,475 shares of Series A Convertible Preferred Stock and a warrant to purchase

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1,019,368 shares of Common Stock with an exercise price of $1.00 per share consistent with the other investors who purchased Series A Convertible Preferred Stock. Such issuance was not considered a debt inducement charge. The Company recorded non-cash interest expense of $37,000 for the period from January 31, 2011 (inception) to December 31, 2011 and $21,000 for the year ended December 31, 2012, and $58,000 for the period from January 31, 2011 (inception) to December 31, 2012.

Due to Related Party

Due to related party consists of cash advances from a member of the Company's Board of Directors during 2011. These amounts were non-interest bearing and were due on demand, with the anticipation that this amount would be converted into equity of the Company under the same terms as the Equity Offering described above. In March 2012 this debt, which amounted to $100,000, was converted into 133,333 shares of Series A Convertible Preferred Stock at a price per share of $0.75 and a warrant to purchase 33,333 shares of Common Stock with an exercise price of $1.00 per share.

9. SERIES A CONVERTIBLE PREFERRED STOCK AND WARRANTS

Series A Convertible Preferred Stock

At December 31, 2012, the Company was authorized to issue 43,000,000 shares of Preferred Stock. All shares of Preferred Stock have a par value of $0.001 per share. The Preferred Stock consists of one series, Series A Convertible Preferred Stock. The rights, preferences, privileges and restrictions granted to and imposed on the Series A Convertible Preferred Stock are described below. The Series A Convertible Preferred Stock does not bear dividends. The Series A Convertible Preferred Stock is only redeemable upon a change in control.

Voting Agreement and Rights

The holders of the Series A Convertible Preferred Stock have the right to one vote for each share of Common Stock into which such share of Series A Convertible Preferred Stock could then be converted. In addition, the holders of the shares of Series A Convertible Preferred Stock, exclusively and as a single class, shall be entitled to elect one director of the Company. The holders of all classes of voting stock (including Series A Convertible Preferred Stock) voting as a single class shall elect the Chief Executive Officer as a director and shall be entitled to elect the balance of directors of the Company. In addition, upon a deemed liquidation event or a sale of the Company, in each case approved by the holders of a majority of the then outstanding shares of Series A Convertible Preferred Stock and the Board of Directors, each stockholder of the Company has agreed to approve such deemed liquidation event or a sale of the Company and sell any shares held by such shareholder in connection with any such transaction.

Conversion

Each share of Series A Convertible Preferred Stock will be convertible into one share of Common Stock, subject to certain anti-dilution protections, at the option of the holder. Each share of Series A Convertible Preferred Stock will automatically convert into one share of Common Stock upon 1) the closing of the sale of shares of Common Stock in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act, resulting in at least $15.0 million of gross proceeds to the Company, or 2) the occurrence of an event specified by a vote or written consent of the holders of a majority of the then outstanding shares of Series A Convertible Preferred Stock.

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Anti-dilution

The Series A Convertible Preferred Stock provides for anti-dilution protection with respect to corporate events such as stock splits, but excluding certain specified events such as issuances pursuant to the 2011 Stock Incentive Plan (the "Plan") or stock options, restricted stock purchases or other similar agreements approved by the Board of Directors and shareholders of the Company which are issued at fair market value at the time of issuance and issuances made in connection with a bona fide acquisition by or of the Company whether by merger or asset purchase with an unaffiliated third party which is approved by the Company's Board of Directors.

Liquidation Preference

In the event of any liquidation, dissolution or winding up of the Company prior to the conversion, the holders of the Series A Convertible Preferred Stock will be entitled to receive, prior and in preference to the holders of the Common Stock, a per share amount equal to the greater of $0.75, the offering price per share as adjusted for any stock splits or dividends, and the amount that would be payable to a holder of the Series A Convertible Preferred Stock had all of the shares of Series A Convertible Preferred Stock been converted to shares of Common Stock.

Right of First Refusal and Co-Sale Agreement

The Series A Convertible Preferred Stock holders along with the holders of Common Stock have entered into a Right of First Refusal and Co-Sale Agreement with the Company in order to provide certain restrictions on the transfer of capital stock and to grant first refusal and co-sale rights to the Company and to the holders of Series A Convertible Preferred Stock.

Investors' Rights Agreement and Registration Rights

The holders of the Series A Convertible Preferred Stock have certain registration rights with respect to the Common Stock into which the shares are convertible. If at any time after the earlier of five years after the date of the Investors' Rights Agreement or 180 days after the effective date of a registration statement, the Company receives a request from the holders of a majority of the shares outstanding securities that are registrable, the Company shall file a registration statement covering those shares. If at any time after the Company is eligible to use a Form S-3 registration statement, the Company receives a request for the holders of at least 20% of the outstanding securities that are registrable, the Company shall file a registration statement on Form S-3 covering those shares so long as certain conditions are met.

Series A Convertible Preferred Stock Transactions

On February 14, 2012, March 23, 2012 and April 4, 2012, the Company completed closings of its private placement offering of Series A Convertible Preferred Stock in the total amount of approximately $19.0 million. The offering price for each unit was $0.75, which consisted of one share of Series A Convertible Preferred Stock and a warrant. Each investor in the offering received a five-year warrant to purchase such number of the Company's shares of Common Stock equal to 25% of the number of shares of Series A Convertible Preferred Stock purchased by such investor at an exercise price equal to $1.00 per share. The placement agent received an 8% placement fee and a 2% corporate finance fee totaling approximately $1.9 million. The net proceeds to the Company of these three closings after offering costs were approximately $17.0 million. The number of shares of Series A Convertible Preferred Stock issued in the three closings was 25,305,583 along with warrants to purchase 6,326,389 shares of Common Stock

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at an exercise price equal to $1.00 per share. The placement agent received warrants to purchase 3,530,559 shares of Common Stock on the same terms and conditions as the other purchasers of Series A Convertible Preferred Stock received in this offering.

On May 18, 2012, the Company completed a direct private placement of its Series A Convertible Preferred Stock in the amount of $1.2 million also at a purchase price of $0.75 per unit. The number of shares of Series A Convertible Preferred Stock issued in the closing was 1,600,000 along with warrants to purchase 400,000 shares of Common Stock at $1.00 per share. On March 23, 2012, the convertible demand promissory with an outstanding principal balance of $3.0 million, plus accrued interest of $58,000, was converted into 4,077,475 shares of Series A Convertible Preferred Stock along with warrants to purchase 1,019,368 shares of Common Stock at an exercise price equal to $1.00 per share. Further, the Company paid $375,000 to the placement agent as compensation for the direct private placement and conversion of the convertible demand promissory note and recorded the compensation as a reduction of the proceeds from the Series A Convertible Preferred Stock and warrants.

In March 2012, an amount of $100,000 due to related party was converted into 133,333 shares of Series A Convertible Preferred Stock and a warrant to purchase 33,333 shares of Common Stock (see Note 8).

Warrants

A total of 7,779,090 warrants to purchase shares of Common Stock at an exercise price equal to $1.00 per share were issued to investors in connection with the issuance of the Company's Series A Convertible Preferred Stock, the conversion of the convertible demand promissory note and the amount due to related party. The Company determined the fair value of the warrants to be approximately $0.10 per warrant, using a Black-Scholes formula with similar assumptions as those utilized for its stock options (See Note 10) and with a fair market value of $0.31 per share for its Common Stock. The total value of these warrants was approximately $775,000.

A total of 3,530,559 warrants to purchase shares of Common Stock at an exercise price equal to $1.00 per share were issued to the placement agent. The total fair market value was approximately $352,000, recorded as offering costs reducing the amount allocated to preferred stock in the offering.

At December 31, 2012, the following warrants were outstanding:

Number of shares underlying warrants	Exercise price per share	Expiration Date
3,030,066	$ 1.00	February 2017
3,180,323	1.00	March 2017
1,052,701	1.00	March 2017
3,646,559	1.00	April 2017
400,000	1.00	July 2017
11,309,649		

10. STOCK-BASED COMPENSATION

2011 Stock Incentive Plan

On April 28, 2011, the Board of Directors adopted the Plan reserving and authorizing up to 5,000,000 shares of Common Stock for stock-based compensation awards to attract, retain and reward

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eligible employees, consultants, and non-employee directors. The options have a contractual term of ten years. Generally, the options vest annually over three years, as determined by the Board of Directors, upon each option grant. On January 10, 2012, the Board of Directors and stockholders of the Company approved an amendment to the Plan authorizing an increase in the aggregate number of shares reserved for issuance under the Plan from 5,000,000 to 8,000,000 shares of Common Stock. As of December 31, 2012, there were 400,000 shares remaining under the Plan available for future issuance.

The estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized was as follows:

	Period from January 31, 2011 (Inception) to December 31, 2011	Year Ended December 31, 2012	Period from January 31, 2011 (Inception) to December 31, 2012
Research and development	$ 743,569	$ 129,065	$ 872,634
General and administrative	231,760	459,064	690,824
Total stock-based compensation	$ 975,329	$ 588,129	$ 1,563,458

A summary of option activity pursuant to the Plan is as follows:

	Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Opening balance, January 31, 2011	—	$ —	
Granted	475,000	0.12	9.55
Balance, December 31, 2011	475,000	0.12	
Granted	4,125,000	0.25	
Forfeitures	—	—	
Balance, December 31, 2012	4,600,000	$ 0.23	9.18
Vested or expected to vest at December 31, 2012	4,600,000	$ 0.23	9.18
Exercisable at December 31, 2012	247,490	$ 0.22	8.59

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The per-share weighted-average fair value of the options granted during 2011 and 2012 was estimated at $0.25 and $0.21, respectively, on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2011	**2012**
Risk-free interest rate	1.14 - 2.16%	0.85 - 1.14%
Expected term of options (in years)	6.0 - 10.0	6.0 - 10.0
Expected stock price volatility	70.0%	70.0%
Expected annual dividend yield	0.00%	0.00%

The valuation assumptions were determined as follows:

- Risk-free interest rate: The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

- Expected term of options: The Company estimates the expected life of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin No. 107, whereby, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data.

- Expected stock price volatility: The Company estimated the expected volatility based on actual historical volatility of the stock price of other publicly-traded biotechnology companies engaged in lines of business that are the same or similar to the Company's. The Company calculated the historical volatility of the selected companies by using daily closing prices over a period of the expected term of the associated award. The companies were selected based on their enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the associated award. A decrease in the selected volatility would decrease the fair value of the underlying instrument.

- Expected annual dividend yield: The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed and expected dividend yield of 0.0%.

The Company considered numerous objective and subjective factors in the assessment of fair value of its Common Stock, including the price for the Company's Series A Convertible Preferred Stock that was sold to investors and the rights, preferences and privileges of the Series A Convertible Preferred Stock and Common Stock, the Company's financial condition and results of operations during the relevant periods, including the status of the development of the Company's product candidates, and the status of strategic initiatives. These estimates involve a significant level of judgment.

Options Granted Outside of the 2011 Stock Incentive Plan

On May 8, 2012 the Board of Directors approved three grants of non-qualified stock options aggregating 4,700,000 to the President and Chief Executive Officer and two non-employee directors of the Company at $0.31 per share, one-third vesting on three consecutive annual anniversaries.

CERECOR INC.
(A Development Stage Entity)

Notes to Financial Statements — (Continued)

December 31, 2012

A summary of option activity outside of the Plan is as follows:

	Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Opening balance, January 31, 2011	—	$ —	
Authorized	—	—	
Granted	—	—	
Balance, December 31, 2011	—	—	
Granted	4,700,000	0.31	
Forfeitures	—	—	
Balance, December 31, 2012	4,700,000	$ 0.31	9.17
Vested or expected to vest at December 31, 2012	4,700,000	$ 0.31	9.17
Exercisable at December 31, 2012	—	—	

These options expire in February 2022. The aggregate intrinsic value for options outstanding at December 31, 2012 was $354,000. The per-share weighted-average fair value of the options granted outside of the Plan during 2012 was estimated at $0.19 using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31, 2012
Risk-free interest rate	0.85-1.14%
Expected term of options (in years)	6.0-10.0
Expected stock price volatility	70.0%
Expected annual dividend yield	0.00%

As of December 31, 2012, there was $1.4 million of total unrecognized compensation expense, related to unvested options granted under the Plan, unvested options granted outside of the Plan, and restricted stock to be recognized as follows:

Year ending December 31,	
2013	$ 675,072
2014	620,958
2015	75,202
	$ 1,371,232

CERECOR INC.
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Notes to Financial Statements — (Continued)

December 31, 2012

Restricted Stock

The Company sold 3,000,000 restricted shares (drawn from the Plan) to the President and Chief Executive Officer in 2011. The fair value associated with these restricted shares was approximately $3,000. Since the shares were sold to the executive at the fair value of the shares at the date of grant, there was no compensation expense recognized. These shares originally vested over a three-year period, however, the terms of the grant agreement were modified such that the shares became fully vested in 2011. Per the Plan, the Company may repurchase the restricted Common Stock upon termination of employment for cause at the lesser of a) book value, b) original purchase price, or c) the fair market value of common stock on the date of termination. Since the repurchase of the shares is solely at the option of the Company, the instrument is recorded as an equity instrument. The modification of the vesting terms resulted in stock-based compensation expense of approximately $930,000 equal to the then current fair value of the shares that vested immediately in 2011.

During July and August of 2011 certain issuances of Common Stock totaling 400,000 shares, originally issued in April 2011 to non-employees, were modified as restricted stock and are subject to a three year vesting period. The modification resulted in $18,000, $41,000 and $59,000 of additional research and development expense recorded for the period from January 31, 2011 (inception) to December 31, 2011, the year ended December 31, 2012 and the period from January 31, 2011 (inception) to December 31, 2012, respectively.

11. INCOME TAXES

As of December 31, 2012, the Company had federal net operating loss ("NOL") carryforwards of $4.0 million, state NOL carryforwards of $4.0 million and research and development tax credit carryforwards of $78,000, which are available to reduce future taxable income. The federal NOL and tax credit carryforwards will begin to expire at various dates starting in 2031. The state NOL carryforwards will begin to expire at various dates starting in 2031. The NOL 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 the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized. The Company recognized no material adjustment for unrecognized income tax benefits. Through December 31, 2012, the Company had no unrecognized tax benefits or related interest and penalties accrued.

CERECOR INC.
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Notes to Financial Statements — (Continued)

December 31, 2012

The significant components of the Company's deferred tax assets are comprised of the following:

	December 31,	
	2011	**2012**
Deferred tax assets:		
Net operating losses	$ 219,000	$ 1,576,000
Research and development credits	78,000	78,000
Research and development expenses	566,000	3,017,000
Accrued expenses	49,000	117,000
Stock compensation	385,000	617,000
Amortization expense	155,000	186,000
Total deferred tax assets	1,452,000	5,591,000
Deferred tax liabilities:		
Depreciation	(1,000)	(5,000)
Total deferred tax liabilities	(1,000)	(5,000)
Net deferred tax assets	1,451,000	5,586,000
Less valuation allowance	(1,451,000)	(5,586,000)
Net deferred tax asset	$ —	$ —

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2011 and 2012, respectively, because the Company's management has determined that is it more likely than not that these assets will not be fully realized.

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,	
	2011	**2012**
Percent of pre-tax income:		
U.S. federal statutory income tax rate	31.2%	31.2%
State taxes, net of federal benefit	8.3%	8.2%
Research and development credit	2.2%	0.0%
Change in valuation allowance	(41.7)%	(39.4)%
Effective income tax rate	0.0%	0.0%

12. COMMITMENTS AND CONTINGENCIES

Offer Letters

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

CERECOR INC.
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Notes to Financial Statements — (Continued)

December 31, 2012

Office Lease

On May 9, 2011, the Company entered into an agreement with the Maryland Economic Development Corporation for the use of office space. Rent expense amounted to approximately $10,000 and $67,000 for the period from January 31, 2011 (inception) to December 31, 2011 and the year ended December 31, 2012, respectively, and approximately $77,000 for the period from January 31, 2011 (inception) to December 31, 2012. The Company's lease commitment for this office space in 2013 was $80,000, and the agreement expired in 2013.

13. SUBSEQUENT EVENTS

The Company has completed an evaluation of all subsequent events through December 20, 2013, the date on which these financial statements were available to be issued, to ensure that these financial statements include appropriate disclosure of events both recognized in the financial statements as of December 31, 2012 and events which occurred subsequently but were not recognized in the financial statements. The Company has concluded that no subsequent events have occurred that require disclosure, except as disclosed within these financial statements.

In March 2013, we entered into an exclusive license agreement with Merck pursuant to which Merck granted us rights relating to certain small molecule compounds. In consideration of the license, we are required to make an initial payment of $1,500,000. Pursuant to the license agreement we paid $750,000 and upon achievement of FDA acceptance of Merck pre-clinical data and FDA approval of a Phase 3 clinical trial we will pay an additional $750,000. Additional payments may be due upon achievement of development and regulatory milestones, including first commercial sale. Upon commercialization of an NR2B Product, we are obligated to pay Merck milestones and royalties on net sales.

In March 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. We made a $200,000 upfront payment to Merck. Under the agreement we are required to pay milestone payments upon achievement of various development and regulatory milestones. Upon commercialization of a COMT Product, we are obligated to pay Merck a royalty on net sales of a COMT Product.

In August 2013, the Company completed a private equity offering which resulted in gross proceeds of $6.8 million. The offering price for each unit was $0.75, which consisted of one share of Series A-1 Convertible Preferred Stock and a warrant. The number of shares of Series A-1 Convertible Preferred Stock issued was 9,074,511 shares and investor warrants to purchase 2,268,573 shares of Common Stock with an initial exercise price equal to (i) $1.00 per share of Common Share if such warrant is exercised prior to a qualified initial public offering or (ii) the public offering price for a share of Common Stock sold in a qualified initial public offering if such warrant is exercised after such qualified initial public offering, in each instance, subject to further adjustments as set forth in such warrants. The warrants expire on the fifth anniversary from their original issuance date. The net proceeds to the Company after offering costs was approximately $6.1 million. The placement agent received warrants to purchase 680,588 shares of Common Stock priced at $1.00 per share. In addition, for any investor of Series A Convertible Preferred Stock who also participated in the Series A-1 Convertible Preferred Stock offering, the Company amended the terms of the original warrants issued with respect to such Series A Convertible Preferred Stock in 2012 reducing the exercise price from $1.00 per share of Common Stock

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Notes to Financial Statements — (Continued)

December 31, 2012

to $0.50 per share of Common Stock provided that such investor purchased a minimum of 40% of their original Series A Convertible Preferred Stock investment. Further, the shares of Series A-1 Convertible Preferred Stock shall initially accrue dividends at a rate of 2.5% per annum, payable solely in shares of Common Stock, and could potentially increase up to 12.5% per annum if the Company does not file a registration statement with the Securities and Exchange Commission or does not complete a qualified Initial Public Offering by certain dates. Accruing Common Stock dividends shall only be payable upon the conversion of Series A-1 Convertible Preferred Stock into Common Stock.

In August 2013, the Company entered into a five year lease of office space located in Baltimore, Maryland. The lease commenced on October 24, 2013 with a monthly rent expense of approximately $12,000.

CERECOR INC.
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Balance Sheets

	December 31, 2012	September 30, 2013 (unaudited)	Pro Forma September 30, 2013 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 9,519,661	$ 6,340,269	$
Prepaid expenses and other current assets	429,965	676,626	
Total current assets	9,949,626	7,016,895	
Restricted cash	—	175,000	
Property and equipment, net	56,752	48,596	
Other assets	13,310	13,310	
Total assets	$ 10,019,688	$ 7,253,801	$
Liabilities, convertible preferred stock and stockholders' deficit			
Current liabilities:			
Accounts payable	$ 821,114	$ 943,130	$
Accrued expenses and other current liabilities	722,680	1,121,087	
Series A-1 warrant liability	—	310,467	
Total current liabilities	1,543,794	2,374,684	
Convertible Preferred Stock:			
Series A — $0.001 par value; 43,000,000 and 31,500,000 shares authorized at December 31, 2012 and September 30, 2013, respectively, 31,116,391 shares issued and outstanding at December 31, 2012 and September 30, 2013 and no shares issued and outstanding at September 30, 2013, (pro forma) (aggregate liquidation preference of $23,337,293 at September 30, 2013)	19,856,632	19,856,632	
Series A-1 — $0.001 par value; 0 and 20,000,000 shares authorized at December 31, 2012 and September 30, 2013, respectively, 0 and 9,074,511 shares issued and outstanding at December 31, 2012 and September 30, 2013, respectively and no shares issued and outstanding at September 30, 2013, (pro forma) (aggregate liquidation preference of $6,823,526 at September 30, 2013)	—	5,830,424	
Total convertible preferred stock	19,856,632	25,687,056	
Stockholders' deficit:			
Common Stock — $0.001 par value, 87,000,000 and 167,000,000 shares authorized at December 31, 2012 and September 30, 2013, respectively, 18,000,000 shares issued and outstanding at December 31, 2012 and September 30, 2013 and shares authorized, shares issued and outstanding at September 30, 2013, (pro forma)	18,000	18,000	
Preferred Stock — $0.001 par value, no shares authorized, issued and outstanding at December 31, 2012 and September 30, 2013, shares authorized and no shares issued and outstanding pro forma	—	—	
Additional paid-in capital	2,574,040	3,116,595	
Deficit accumulated during the development stage	(13,972,778)	(23,942,534)	
Total stockholders' deficit	(11,380,738)	(20,807,939)	
Total liabilities, convertible preferred stock and stockholders' deficit	$ 10,019,688	$ 7,253,801	$

See accompanying notes to financial statements.

CERECOR INC.
(A Development Stage Entity)

Unaudited Statements of Operations

	Nine Months Ended September 30,		Period From January 30, 2011 (Inception) to September 30, 2013
	2012	2013	
Grant revenue	$ 82,760	$ —	$ 292,476
Operating expenses:			
Research and development	6,719,239	7,054,223	18,348,923
General and administrative	1,323,172	2,923,070	5,858,231
Total operating expenses	8,042,411	9,977,293	24,207,154
Loss from operations	(7,959,651)	(9,977,293)	(23,914,678)
Other income (expense):			
Interest expense	(21,007)	—	(58,106)
Interest and other income	17,241	7,537	30,250
Total other income (expense)	(3,766)	7,537	(27,856)
Net loss	(7,963,417)	(9,969,756)	(23,942,534)
Deemed dividend	—	(81,963)	(81,963)
Net loss attributable to Common Stockholders	$ (7,963,417)	$ (10,051,719)	$ (24,024,497)
Per share information:			
Net loss per share of Common Stock, basic and diluted	$ (0.45)	$ (0.57)	
Weighted-average shares outstanding, basic and diluted	17,623,813	17,723,901	
Pro forma net loss per share of Common Stock, basic and diluted (unaudited)		$	
Pro forma basic and diluted weighted-average shares outstanding (unaudited)			

See accompanying notes to financial statements.

CERECOR INC.
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Unaudited Statements of Convertible Preferred Stock and Stockholders' Deficit

For the Period from January 31, 2011 (Inception) to September 30, 2013

	Convertible Preferred Stock — Series A		Convertible Preferred Stock — Series A-1		Stockholders' Deficit				
					Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
Balance, January 31, 2011 (Inception)	—	$ —	$ —	$ —	—	$ —	$ —	$ —	$ —
Issuance of Common Stock	—	—	—	—	18,000,000	18,000	—	—	18,000
Stock-based compensation expense	—	—	—	—	—	—	975,329	—	975,329
Net loss	—	—	—	—	—	—	—	(3,483,179)	(3,483,179)
Balance, December 31, 2011	—	—	—	—	18,000,000	18,000	975,329	(3,483,179)	(2,489,850)
Issuance of Series A convertible preferred stock, net of issuance costs	31,116,391	19,856,632	—	—	—	—	—	—	—
Issuance of Common Stock warrants	—	—	—	—	—	—	1,010,582	—	1,010,582
Stock-based compensation expense	—	—	—	—	—	—	588,129	—	588,129
Net loss	—	—	—	—	—	—	—	(10,489,599)	(10,489,599)
Balance, December 31, 2012	31,116,391	19,856,632	—	—	18,000,000	18,000	2,574,040	(13,972,778)	(11,380,738)
Issuance of Series A-1 convertible preferred stock, net of issuance costs	—	—	9,074,511	5,830,424	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	542,555	—	542,555
Net loss	—	—	—	—	—	—	—	(9,969,756)	(9,969,756)
Balance, September 30, 2013	31,116,391	$ 19,856,632	9,074,511	$ 5,830,424	18,000,000	$ 18,000	$ 3,116,595	$ (23,942,534)	$ (20,807,939)

See accompanying notes to financial statements.

CERECOR INC.
(A Development Stage Entity)

Unaudited Statements of Cash Flows

	Nine Months Ended September 30,		Period From January 30, 2011 (Inception) to September 30, 2013
	2012	2013	
Operating activities			
Net loss	$ (7,963,417)	$ (9,969,756)	$ (23,942,534)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	10,646	13,866	30,973
Stock-based compensation expense	398,305	542,555	2,106,013
Non-cash interest expense	21,007	—	58,106
Offering costs related to warrant liability	—	25,811	25,811
Changes in operating assets and liabilities:			
Prepaid expenses and Other assets	7,385	(246,662)	(689,938)
Restricted cash	—	(175,000)	(175,000)
Accrued liabilities and employee benefits	979,906	398,408	1,221,089
Accounts payable	90,891	122,016	943,130
Deferred revenue	(82,760)	—	—
Net cash used in operating activities	(6,538,037)	(9,288,762)	(20,422,350)
Investing activities			
Purchase of property and equipment	(7,890)	(5,710)	(79,569)
Net cash provided by (used in) investing activities	(7,890)	(5,710)	(79,569)
Financing activities			
Proceeds from issuance of convertible promissory note	—	—	3,000,000
Proceeds from issuance of Common Stock	—	—	18,000
Proceeds from issuance of Series A Convertible Preferred Stock, and Common Stock warrants, net of offering costs	17,709,108	—	17,709,108
Proceeds from issuance of Series A-1 Convertible Preferred Stock, and Common Stock warrants, net of offering costs	—	6,115,080	6,115,080
Net cash provided by financing activities	17,709,108	6,115,080	26,842,188
(Decrease) increase in cash and cash equivalents	11,163,181	(3,179,392)	6,340,269
Cash and cash equivalents at beginning of period	1,111,200	9,519,661	—
Cash and cash equivalents at end of period	$ 12,274,381	$ 6,340,269	$ 6,340,269
Supplemental disclosures of cash flow information			
Notes payable converted to Convertible Series A Stock	$ 3,058,106	$ —	$ 3,058,106

See accompanying notes to financial statements.

CERECOR INC.
(A Development Stage Entity)

Notes to Unaudited Financial Statements September 30, 2013

1. BUSINESS DESCRIPTION OF BUSINESS AND ORGANIZATION

Cerecor Inc. (the "Company" or "Cerecor") was incorporated on January 31, 2011 in Delaware as Ceregen Corporation and subsequently changed the name to Cerecor Inc in March 2011. The Company is a clinical-stage biopharmaceutical company committed to becoming a leader in the development and commercialization of innovative drugs that address the needs of underserved patients with nervous system disorders. The Company's operations since inception have been limited to organizing and staffing the Company, acquiring rights to and developing certain product candidates and its product platform, business planning and raising capital. Accordingly, the Company is considered to be in the development stage as defined by Accounting Standards Codification ("ASC") 915, *Development Stage Entities* ("ASC 915"). The Company's principal office is in Baltimore, Maryland. The Company's revenue to date has been derived solely from research grants.

Liquidity

The Company has incurred recurring operating losses since inception. For the nine months ended September 30, 2013, the Company incurred a net loss of $10.0 million and as of September 30, 2013, the Company had generated an accumulated deficit of $23.9 million. The Company has not generated any product revenue to date. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to the clinical development of its product candidates, its product platform and its preclinical programs, business development and the development of its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy. To fully execute its business plan, the Company will need to complete certain research and development activities, clinical trials and obtain marketing approval for its product candidates, which may span many years, and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company plans to meet its capital requirements primarily through a combination of equity and debt financings, collaborations, strategic alliances and marketing distribution or licensing arrangements and in the longer term, revenue from product sales to the extent its product candidates receive marketing approval and are commercialized. There can be no assurance, however, that the Company will be successful in obtaining financing at the level needed to sustain operations or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow. The Company currently anticipates that its cash and cash equivalents will be sufficient to meet its anticipated cash requirements through the first quarter of 2014.

2. SIGNIFICANT ACCOUNTING POLICIES BASIS OF PRESENTATION

The accompanying financial statements have been prepared in conformity with U. S. generally accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Unaudited Pro Forma Information

On December 17, 2013, the Company's Board of Directors authorized management of the Company to confidentially submit a registration statement to the Securities and Exchange Commission (the "SEC") for the Company to sell shares of its Common Stock (the "Common Stock") to the public. The unaudited pro forma balance sheet information as of September 30, 2013 assumes the conversion of all outstanding shares of the Company's preferred stock as of that date into shares of the Company's Common Stock Common Stock. The unaudited pro forma net loss per share is computed

CERECOR INC.
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Notes to Unaudited Financial Statements September 30, 2013 — (Continued)

using the weighted-average number of shares of Common Stock outstanding and gives effect to the automatic conversion of all outstanding shares of the Company's (i) Series A Convertible Preferred Stock into an aggregate of 31,116,391 shares of the Company's Common Stock, and (ii) Series A-1 Convertible Preferred Stock, including accrued dividends, into an aggregate of shares of the Company's Common Stock and assuming an initial public offering price of $ per share and assuming that the closing of the public offering had occurred on January 1, 2013 or the date of original issuance, if later.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, other comprehensive income and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to clinical trial accruals. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

In addition, the Company utilizes estimates and assumptions in determining the fair value of its Common Stock. The Company granted stock options at exercise prices not less than the fair value of its Common Stock as determined by the Board of Directors, with input from management. Management uses the assistance of a third-party valuation firm in estimating the fair value of the Common Stock. The Board of Directors has determined the estimated fair value of the Common Stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the historic prices at which the Company sold shares of its Series A Convertible Preferred Stock and Series A-1 Convertible Preferred Stock.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2012 included elsewhere in this prospectus. Since the date of those financial statements, there have been no significant changes to the Company's significant accounting policies.

Restricted Cash

During the third quarter of 2013, the Company entered into a lease for new office space for its principal offices in Baltimore, Maryland. The Company has provided the landlord with a Letter of Credit in the amount of $175,000 as security by the Company of all of the terms of this Lease. The funds are invested in a certificate of deposit. Provided there has been no event of default by the Company, the amount of the Letter of Credit shall be reduced by one-third ($58,000) at the end of each of the first three years of the lease term. At the expiration of the third year of the lease term, the Company shall deposit with Landlord the sum of $13,000 as a security deposit.

Grant Revenue Recognition

The Company recognizes grant revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable, and collectability is reasonably assured. In August 2011, the Company received a research grant from the National Heart, Lung, and Blood Institute of the National Institute of Health to assist in the funding of certain research activities from August 2011 through July 2012. The amount of the award was $292,000 which was received in 2011. The Company has recognized revenue in the amounts of $83,000, for the

CERECOR INC.
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Notes to Unaudited Financial Statements September 30, 2013 — (Continued)

nine months ended September 30, 2012, and $292,000 from January 31, 2011 (inception) through September 30, 2013. The Company recognizes revenue under grants in earnings in the period in which the related expenditures are incurred.

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 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, 2012, the Company does not believe any material uncertain tax positions are present. Accordingly, interest and penalties have not been accrued due to an uncertain tax position and the fact the Company has reported tax losses since inception.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company and the chief executive officer view the Company's operations and manage its business as one operating segment. All long-lived assets of the Company reside in the United States.

Recent Accounting Pronouncements

On April 5, 2012, the Jump-Start Our Business Startups Act (the "JOBS Act") was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." The Company is considered an emerging growth company, but has elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. As a result, the Company will comply with new

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or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

In June 2011, FASB issued ASU No. 2011-05, *Comprehensive Income (ASC Topic 220): Presentation of Comprehensive Income* ("ASU 2011-05"). This accounting update eliminates the option to present the components of other comprehensive income as part of the statement of stockholders' equity. Instead, comprehensive income must be presented in either a single continuous statement of comprehensive income, which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements. ASU 2011-05 was effective for fiscal periods beginning after December 15, 2011, with early adoption permitted. The Company's retrospective adoption of ASU 2011-05 did not have a significant impact on its financial position, results of operations or cash flows.

In February 2013, FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* ("ASU 2013-02"). ASU 2013-02 requires companies to present either in a single note or parenthetically on the face of the financial statements, the effect of significant amounts reclassified from each component of accumulated other comprehensive income based on its source and the income statement line items affected by the reclassification. This guidance is effective for annual reporting periods beginning after December 15, 2012. The Company believes the adoption of this standard will not have a significant impact on its financial position, results of operations or cash flows.

3. NET LOSS PER COMMON SHARE

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Nine Months Ended September 30,	
	2012	**2013**
Basic and diluted net loss per common share calculation:		
Net loss	$ (7,963,417)	$ (9,969,756)
Deemed dividend	—	(81,963)
Net loss attributable to Common Stockholders	$ (7,963,417)	$ (10,051,719)
Weighted-average common shares outstanding	17,623,813	17,723,901
Net loss per share of Common Stock — basic and diluted	$ (0.45)	$ (0.57)

The following outstanding securities at September 30, 2012 and 2013 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

Convertible preferred stock	31,116,391	40,190,902
Unvested restricted stock	300,000	200,000
Options outstanding	8,400,000	10,687,375
Warrants	11,309,649	14,258,810
Total	51,126,040	65,337,087

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

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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.

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 as of December 31, 2012.

	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*	$ 9,440,841	$ —	$ —

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 as of September 30, 2013.

	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 6,004,401	$ —	$ —
Liabilities			
Series A-1 Warrant Liability	$ —	$ —	$ 310,467

* Investments in money market funds are reflected in cash and cash equivalents in the accompanying Balance Sheets.

Level 3 Valuation

The Series A-1 warrant liability is recorded in its own line item on the Company's Balance Sheets. The warrant liability is marked-to-market each reporting period with the change in fair value recorded to other loss in the Statement of Operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument. The fair value of the

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warrant liability is estimated using a Black-Scholes pricing model. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants to purchase shares of Common Stock as of September 30, 2013, include (i) volatility (70.0%), (ii) risk free interest rate (1.39%), (iii) strike price ($1.00), (iv) fair value of Common Stock ($0.32), (v) expected life (5.0). The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the Series A-1 warrant liability for the nine months ended September 30, 2013:

	Level 3 Series A Warrant Liability
Balance at December 31, 2011 and 2012	$ 0
Warrants issued in connection with Series A-1 preferred stock	310,467
Balance at September 30, 2013	$ 310,467

No other changes in valuation techniques or inputs occurred during the nine months ended September 30, 2013. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2013.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2012	September 30, 2013
Compensation and benefits	$ 336,185	$ 369,142
Research and development expenses	372,017	678,553
Other	14,478	73,392
Total accrued expenses and other current liabilities	$ 722,680	$ 1,121,087

6. ASSET ACQUISITIONS AND LICENSE AGREEMENT

In May 2011, the Company entered into an asset purchase agreement with Fells Laboratories LLC ("Fells") for the acquisition of certain assets owned or licensed by Fells, all related to a compound known as FP01. The Company also assumed certain contractual obligations relating to FP01. The principal assets acquired consisted of three patents owned by Fells and a license with Johns Hopkins University ("JHU"), which includes rights to two additional patents. According to the terms of the Agreement, the Company paid $540,000, which consisted of a $340,000 upfront payment in May 2011, which was expensed as research and development during the period from January 31, 2011 (inception) to December 31, 2011, and a $200,000 milestone payment in July 2012, which was expensed as research and development during the nine months ended September 30, 2012, upon the successful completion of the prototype of the formulation of FP01. The Company could be required to pay up to an additional $1.9 million to Fells upon the achievement of certain contingent development and regulatory milestones.

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The Company accounted for this transaction as an asset acquisition because it only acquired the assigned rights and technology and did not acquire any processes or activities. The majority shareholder of Fells is the Company's President and Chief Executive Officer.

Pursuant to the terms of the license agreement between JHU and Fells, which the Company assumed in the asset acquisition, the Company may be required to make contingent milestone payments to JHU of up to $375,000 upon the achievement of certain development and regulatory milestones. During 2013, the Company has paid JHU $5,000, which has been recorded as research and development expenses in the accompanying statement of operations. The Company is not currently developing FP01 and does not expect to pay any additional fees to Fells or JHU unless the Company out-licenses FP01 to a third party for development.

In March 2013, we entered into an exclusive license agreement with Merck pursuant to which Merck granted us rights relating to certain small molecule compounds. In consideration of the license, we are required to make an initial payment of $1,500,000. Pursuant to the license agreement we paid $750,000 and upon achievement of FDA acceptance of Merck pre-clinical data and FDA approval of a Phase 3 clinical trial we will pay an additional $750,000. Additional payments may be due upon achievement of development and regulatory milestones, including first commercial sale. Upon commercialization of an NR2B Product, we are obligated to pay Merck milestones and royalties on net sales.

In March 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. We made a $200,000 upfront payment to Merck. Under the agreement we are required to pay milestone payments upon achievement of various development and regulatory milestones. Upon commercialization of a COMT Product, we are obligated to pay Merck a royalty on net sales of a COMT Product.

7. DEBT

Convertible Promissory Note — Due to Related Party

On April 29, 2011, the Company executed a convertible demand promissory note with an affiliate of a member of the Company's Board of Directors. Under this note, advances were made to the Company in April through November 2011 for an aggregate principal amount of $3.0 million. The convertible demand promissory note carried a 3% annual interest rate compounded quarterly on the unpaid principal amount. All principal and accrued interest was payable on demand. The convertible demand promissory note provided for the automatic conversion of the outstanding principal and unpaid interest upon the completion of an equity offering that generated aggregate net proceeds in excess of $10.0 million ("Equity Offering"). In the event of this conversion, the convertible demand promissory note would automatically convert into equity instruments equivalent to those issued in the Equity Offering at a conversion price equal to lowest price per share paid by other investors and at the same terms and conditions as the other investors.

The initial terms of the convertible demand promissory note called for an automatic conversion into shares of Common Stock at a price per share of $1.00, at December 31, 2011, if an Equity Offering had not occurred. In December 2011, the date for the automatic conversion of the convertible demand promissory note into shares of Common Stock was extended to June 30, 2012. On March 23, 2012, pursuant to the terms for automatic conversion upon an Equity Offering, the outstanding principal and unpaid interest converted into shares of Series A Convertible Preferred Stock. Upon conversion the

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holder received 4,077,475 shares of Series A Convertible Preferred Stock and a warrant to purchase 1,019,368 shares of Common Stock with an exercise price of $1.00 per share consistent with the other investors who purchased Series A Convertible Preferred Stock. Such issuance was not considered a debt inducement charge. The Company recorded non-cash interest expense of $21,000 for the nine months ended September 30, 2012, and $58,000 for the period from January 31, 2011 (inception) to September 30, 2013.

Due to Related Party

Due to related party consists of cash advances from a member of the Company's Board of Directors during 2011. These amounts were non-interest bearing and were due on demand, with the anticipation that this amount would be converted into equity of the Company under the same terms as the Equity Offering described above. In March 2012 this debt, which amounted to $100,000, was converted into 133,333 shares of Series A Convertible Preferred Stock at a price per share of $0.75 and a warrant to purchase 33,333 shares of Common Stock with an exercise price of $1.00 per share.

8. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

Series A Convertible Preferred Stock

At September 30, 2013, the Company was authorized to issue two classes of stock, Common Stock and Preferred Stock. The total number of shares of capital stock the Company was authorized to issue was 249,500,000 of which 167,000,000 was Common and 82,500,000 was Preferred. All shares of Common and Preferred Stock has a par value of $0.001 per share. 31,500,000 of the authorized shares of Preferred Stock are designated as Series A Convertible Preferred Stock and 20,000,000 of the authorized shares of Preferred Stock are hereby designated as Series A-1 Convertible Preferred Stock.

At December 31, 2012, the Company was authorized to issue 43,000,000 shares of Series A Convertible Preferred Stock. During 2013, the Company issued 9,074,511 shares of Series A-1 Convertible Preferred Stock as described below.

The rights, preferences, privileges and restrictions granted to and imposed on the Series A and Series A-1 Convertible Preferred Stock ("Series Preferred Stock") are described below.

Voting Agreement and Rights

The holders of the Series Preferred Stock have the right to one vote for each share of Common Stock into which such share of Series Preferred Stock could then be converted. In addition, the holders of the shares of Series Preferred Stock, exclusively and as a single class, shall be entitled to elect one director of the Company. The holders of all classes of voting stock (including Series Preferred Stock) voting as a single class shall elect the Chief Executive Officer as a director and shall be entitled to elect the balance of directors of the Company. In addition, upon a deemed liquidation event or a sale of the Company, in each case approved by the holders of a majority of the then outstanding shares of Series Preferred Stock and the Board of Directors, each stockholder of the Company has agreed to approve such deemed liquidation event or a sale of the Company and sell any shares held by such shareholder in connection with any such transaction.

Conversion

Each share of Series Preferred Stock will be convertible into one share of Common Stock, subject to certain anti-dilution protections, at the option of the holder. Each share of Series Preferred Stock will

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automatically convert into one share of Common Stock upon 1) the closing of the sale of shares of Common Stock in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act, resulting in at least $15.0 million of gross proceeds to the Company, or 2) the occurrence of an event, specified by a vote or written consent of the holders of a majority of the then outstanding shares of Series Preferred Stock.

Anti-dilution

The Series Preferred Stock provides for anti-dilution protection with respect to corporate events such as stock splits, but excluding certain specified events such as issuances pursuant to the 2011 Stock Incentive Plan (the "Plan") or stock options, restricted stock purchases or other similar agreements approved by the Board of Directors and shareholders of the Company which are issued at fair market value at the time of issuance and issuances made in connection with a bona fide acquisition by or of the Company whether by merger or asset purchase with an unaffiliated third party which is approved by the Company's Board of Directors. The Series A-1 Convertible Preferred Stock also provides for anti-dilution protection depending on the offering price of the Company's Common Stock in a qualified Initial Public Offering.

Dividends

The Series A Convertible Preferred Stock does not bear dividends. The Series A-1 Convertible Preferred Stock shall initially accrue dividends payable solely in shares of Common Stock at a rate of 2.5% per annum and could potentially increase up to 12.5% per annum if the Company does not file a registration statement with the Securities and Exchange Commission or does not complete a qualified Initial Public Offering by certain dates. Accruing Common Stock dividends shall only be payable upon the conversion of Series A-1 Convertible Preferred Stock into Common Stock or certain deemed liquidation events. At September 30, 2013, 23,523 shares of Common Stock were contingently issuable upon conversion. Dividends on the Series A Convertible Preferred Stock are considered a conversion rate adjustment, therefore no dividends have been accrued.

Liquidation Preference

In the event of any liquidation, dissolution or winding up of the Company prior to the conversion, the holders of the Series Preferred Stock will be entitled to receive, prior and in preference to the holders of the Common Stock, a per share amount equal to the greater of $0.75, the offering price per share as adjusted for any stock splits or dividends, and the amount that would be payable to a holder of the Series Preferred Stock had all of the shares of Series Preferred Stock been converted to shares of Common Stock.

Right of First Refusal and Co-sale Agreement

The Series Preferred Stock holders along with the holders of Common Stock have entered into a Right of First Refusal and Co-Sale Agreement with the Company in order to provide certain restrictions on the transfer of capital stock and to grant first refusal and co-sale rights to the Company and to the holders of Preferred Stock.

Investors' Rights Agreement and Registration Rights

The holders of the Series A Convertible Preferred Stock have certain registration rights with respect to the Common Stock into which the shares are convertible. If at any time after the earlier of

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five years after the date of the Investors' Rights Agreement or 180 days after the effective date of a registration statement, the Company receives a request from the holders of a majority of the shares outstanding securities that are registrable, the Company shall file a registration statement covering those shares. If at any time after the Company is eligible to use a Form S-3 registration statement, the Company receives a request for the holders of at least 20% of the outstanding securities that are registrable, the Company shall file a registration statement on Form S-3 covering those shares so long as certain conditions are met.

Series A Convertible Preferred Stock Transactions

On February 14, 2012, March 23, 2012 and April 4, 2012, the Company completed closings of its private placement offering of Series A Convertible Preferred Stock in the total amount of approximately $19.0 million. The offering price for each unit was $0.75, which consisted of one share of Series A Convertible Preferred Stock and a warrant. Each investor in the offering received a five-year warrant to purchase such number of the Company's shares of Common Stock equal to 25% of the number of shares of Series A Convertible Preferred Stock purchased by such investor at an exercise price equal to $1.00 per share. The placement agent received an 8% placement fee and a 2% corporate finance fee totaling approximately $1.9 million. The net proceeds to the Company of these three closings after offering costs were approximately $17.0 million. The number of shares of Series A Convertible Preferred Stock issued in the three closings was 25,305,583 along with investor warrants to purchase 6,326,389 shares of Common Stock at an exercise price equal to $1.00 per share. The placement agent received warrants to purchase 3,530,559 shares of Common Stock on the same terms and conditions as the other warrants that the purchasers of Series A Convertible Preferred Stock received in this offering.

On May 18, 2012, the Company completed a direct private placement of its Series A Convertible Preferred Stock in the amount of $1.2 million also at a purchase price of $0.75 per unit. The number of shares of Series A Convertible Preferred Stock issued in the closing was 1,600,000 along with warrants to purchase 400,000 shares of Common Stock at $1.00 per share. On March 23, 2012, the convertible demand promissory with an outstanding principal balance of $3.0 million, plus accrued interest of $58,000, was converted into 4,077,475 shares of Series A Preferred Stock along with warrants to purchase 1,019,368 shares of Common Stock at an exercise price equal to $1.00 per share. Further, the Company paid $375,000 to the placement agent as compensation for the direct private placement and conversion of the convertible demand promissory note and recorded the compensation as a reduction of the proceeds from the Series A Convertible Preferred Stock and warrants. In March 2012, an amount of $100,000 due to related party was converted into 133,333 shares of Series A Convertible Preferred Stock and a warrant to purchase 33,333 shares of common stock (see Note 7).

Series A-1 Convertible Preferred Stock Transaction

In August 2013, the Company completed a $6.8 million private equity offering. The offering price for each unit was $0.75, which consisted of one share of Series A-1 Convertible Preferred Stock and a warrant. The number of shares of Series A-1 Convertible Preferred Stock issued was 9,074,511 shares along with investor warrants to purchase 2,268,573 shares of Common Stock with an initial exercise price equal to (i) $1.00 per share of Common Share if such warrant is exercised prior to a qualified initial public offering or (ii) the public offering price for a share of Common Stock sold in a qualified initial public offering if such warrant is exercised after such qualified initial public offering, in each instance, subject to further adjustments as set forth in such warrants. The warrants expire on the fifth anniversary from their original issuance date. The net proceeds to the Company after offering costs was approximately $6.1 million. The placement agent received warrants to purchase 680,588 shares of

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Common Stock priced at $1.00 per share. In addition, for any investor of Series A Preferred Stock who also participated in the Series A-1 Preferred Stock offering, the Company amended the terms of the original warrants issued with respect to such Series A Preferred Stock in 2012 reducing the exercise price from $1.00 per share of Common Stock to $0.50 per share of Common Stock provided that such investor purchased a minimum of 40% of their original Series A Preferred Stock investment. Further, the Series A-1 shares shall initially accrue Common Stock dividends at a rate of 2.5% per annum and could potentially increase up to 12.5% per annum as described above.

Warrants

During 2012, a total of 7,779,090 warrants to purchase shares of Common Stock at an exercise price equal to $1.00 per share were issued to investors in connection with the issuance of the Company's Series A Convertible Preferred Stock, the conversion of the convertible demand promissory note and the amount due to related party. The Company determined the fair value of the warrants to be approximately $0.10 per warrant. The fair value was calculated using a Black-Scholes pricing model using a fair market value of $0.31 per share for its Common Stock and similar assumptions disclosed later in this note.

In August 2013, a total of 2,268,573 warrants to purchase shares of Common Stock at an exercise price equal to $1.00 per share were issued to investors in connection with the Company's Series A-1 Convertible Preferred Stock. In addition, a total of 680,588 warrants to purchase Common Stock at an exercise price equal to $1.00 per share were issued to the placement agent. The fair value was calculated using a Black-Scholes pricing model using a fair market value of $0.32 per share for its common stock and similar assumptions disclosed later in this note. The total fair value of these warrants on the date of grant was approximately $310,000, recorded as offering costs reducing the amount allocated to preferred stock in the offering. In addition, in the event a holder of the Company's Series A Convertible Preferred Stock purchased a number of shares of Series A-1 Convertible Preferred Stock in an amount equal to at least 40% of the shares of Series A Convertible Preferred Stock owned by such holder, the Company amended the warrant to purchase the Company's Common Stock such holder received in connection with his, her or its purchase of shares of Series A Convertible Preferred Stock such that the exercise price per share of such warrant will be reduced from $1.00 to $0.50. A total of 1,647,766 warrants were amended.

At September 30, 2013, the following warrants were outstanding:

Number of shares underlying warrants issued to investors of Convertible Preferred stock	Exercise price per share	Expiration Date
2,210,290	$ 1.00	February 2017
819,776	0.50	February 2017
3,405,035	1.00	March 2017
827,990	0.50	March 2017
3,646,559	1.00	April 2017
400,000	1.00	July 2017
2,949,160	1.00	August 2018
14,258,810		

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9. STOCK-BASED COMPENSATION

2011 Stock Incentive Plan

On April 28, 2011, the Board of Directors adopted the Plan reserving and authorizing up to 5,000,000 shares of Common Stock for stock-based compensation awards to attract, retain and reward eligible employees, consultants, and non-employee directors. The options have a contractual term of ten years. Generally, the options vest annually over three years, as determined by the Board of Directors, upon each option grant. On January 10, 2012, the Board of Directors and stockholders of the Company approved an amendment to the Plan authorizing an increase in the aggregate number of shares reserved for issuance under the Plan from 5,000,000 to 8,000,000 shares of Common Stock. On May 6, 2013 the Board of Directors approved an Amendment to the Plan authorizing an increase in the aggregate number of shares reserved for issuance under the Plan from 8,000,000 to 19,724,005 shares of Common Stock. As of September 30, 2013, there were 10,736,630 shares of Common Stock available for future issuance under the Plan.

The estimated grant-date fair value of the Company's stock-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized was as follows:

	Nine Months Ended,		Period from January 31, 2011 (Date of Inception) to September 30, 2013
	2012	2013	
Research and development	$ 91,265	$ 124,768	$ 997,401
General and administrative	307,040	417,787	1,108,612
Total stock-based compensation	$ 398,305	$ 542,555	$ 2,106,013

A summary of option activity pursuant to the Plan is as follows:

	Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Balance, December 31, 2012	4,600,000	$ 0.23	9.18
Granted	1,437,375	$ 0.32	
Forfeitures	(50,000)	$ 0.31	
Balance, September 30, 2013	5,987,375	$ 0.25	8.81
Vested or expected to vest at September 30, 2013	5,987,375	$ 0.25	8.81
Exercisable at September 30, 2013	1,542,291	$ 0.21	8.35

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The per-share weighted-average fair value of the options granted during the nine months ended September 30, 2012 and 2013 was estimated at $0.22 and $0.21 per share, respectively, on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2012	**2013**
Risk-free interest rate	0.85 - 1.14%	1.14 - 1.90%
Expected term of options (in years)	6.0 - 100	6.0 - 100
Expected stock price volatility	70.0%	70.0%
Expected annual dividend yield	0.00%	0.00%

The valuation assumptions were determined as follows:

Risk-free interest rate: The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

- Expected term of options: The Company estimates the expected life of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin No. 107, whereby, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data.

- Expected stock price volatility: The Company estimated the expected volatility based on actual historical volatility of the stock price of other publicly-traded biotechnology companies engaged in lines of business that are the same or similar to the Company's. The Company calculated the 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%.

- Estimated forfeiture rate: The Company's estimated annual forfeiture rate on 2012 stock option grants was 0%, based on the historical forfeiture experience.

The Company considered numerous objective and subjective factors in the assessment of fair value of its Common Stock, including the price for the Company's Series A Convertible Preferred Stock that was sold to investors and the rights, preferences and privileges of the preferred stock and Common Stock, the Company's financial condition and results of operations during the relevant periods, including the status of the development of the Company's product candidates, and the status of strategic initiatives. These estimates involve a significant level of judgment.

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As of September 30, 2013, there was $1.1 million of total unrecognized compensation expense, related to unvested options granted under the Plan, options granted outside of the Plan, and restricted stock which will be recognized over the weighted-average remaining period of 1.56 years.

Options Granted Outside of the 2011 Stock Incentive Plan

On May 8, 2012 the Board of Directors approved three grants of non-qualified stock options aggregating 4,700,000 to the Chief Executive Officer and two non-employee directors of the Company at $0.31 per share, vesting equally on three consecutive annual anniversaries. A summary of option activity outside of the Plan is as follows:

	Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Balance, December 31, 2012	4,700,000	$ 0.31	9.17
Granted	—	—	
Forfeitures	—	—	
Balance, September 30, 2013	4,700,000	$ 0.31	8.42
Vested or expected to vest at September 30, 2013	4,700,000	$ 0.31	8.42
Exercisable at September 30, 2013	1,566,667	$ 0.31	8.42

These options expire in February 2022. The aggregate intrinsic value for non-qualified options outstanding at September 30, 2013 was approximately $. The aggregate intrinsic value is calculated as the difference between $, the midpoint of the price range of this offer, and the exercise price of the option, multiplied by the number of options.

Restricted Stock

The Company sold 3,000,000 restricted shares (drawn from the Plan) to the President and Chief Executive Officer in 2011. The fair value associated with these restricted shares was approximately $3,000. Since the shares were sold to the executive at the fair value of the shares at the date of grant, there was no compensation expense recognized. These shares originally vested over a three-year period, however, the terms of the grant agreement were modified such that the shares became fully vested in 2011. Per the Plan, the Company may repurchase the restricted Common Stock upon termination of employment for cause, at the lesser of a) book value, b) original purchase price, or c) the fair market value of common stock on the date of termination. Since the repurchase of the shares is solely at the option of the Company, the instrument is recorded as an equity instrument. The modification of the vesting terms resulted in stock based compensation expense of approximately $930,000 equal to the then current fair value of the shares that vested immediately in 2011.

During July and August of 2011 certain issuances of Common Stock totaling 400,000 shares, originally issued in April 2011 to non-employees, were modified as restricted stock and are subject to a three year vesting period. The modification resulted in $18,000, $41,000 and $59,000 of additional research and development expense recorded for the period from January 31, 2011 (inception) to

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December 31, 2011, the year ended December 31, 2012 and the period from January 31, 2011 (inception) to December 31, 2012, respectively.

10. COMMITMENTS AND CONTINGENCIES

Offer Letters

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

Office Lease

In August 2013, the Company entered into a lease for new corporate office space located in Baltimore, Maryland. The 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. Pursuant to the terms of such lease, the Company's aggregate rental obligation is $712,000 broken down as follows: (i) through the end of the 2013 fiscal year is $107,000, (ii) for one to three years is $448,000, (iii) for three to five years is $157,000 and (iv) for more than five years is $0.

11. SUBSEQUENT EVENTS

The Company has completed an evaluation of all subsequent events through December 20, 2013, the date on which these financial statements were available to be issued, to ensure that these financial statements include appropriate disclosure of events both recognized in the financial statements as of September 30, 2013 and events which occurred subsequently but were not recognized in the financial statements. The Company has concluded that no subsequent events have occurred that require disclosure, except as disclosed within these financial statements.

Table of Contents

Shares

Common Stock

PROSPECTUS

, 2014

Wells Fargo Securities

JMP Securities

Needham & Company

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

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by the registrant. All amounts are estimates except the Securities and Exchange Commission registration fee and the Financial Industry Regulatory Authority, Inc. filing fee.

	Amount
Securities and Exchange Commission registration fee	$ *
Financial Industry Regulatory Authority, Inc. filing fee	*
NASDAQ Capital Market initial listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue Sky fees and expenses	*
Transfer Agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total Expenses	$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty to the corporation or its stockholders, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock purchase or redemption in violation of Delaware corporate law or derived an improper personal benefit. Our amended and restated certificate of incorporation that will be effective upon the closing of this offering provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnify for such expenses which the Court of Chancery or such other court shall deem proper.

Our amended and restated certificate of incorporation that will be effective upon the closing of the offering provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Our amended and restated certificate of incorporation that will be effective upon the closing of the offering also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If we do not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

The underwriting agreement we will enter into in connection with the offering of common stock being registered hereby provides that the underwriters will indemnify, under certain conditions, our directors and officers (as well as certain other persons) against certain liabilities arising in connection with such offering.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of common stock and preferred stock issued, and options granted, by us within the past three years that were not registered under the Securities Act of 1933, as amended (the "Securities Act"). Also included is the consideration, if any, received by us for such shares and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Issuances of Securities

In August 2013, we issued and sold to investors at a purchase price of $0.75 per unit an aggregate of 9,074,511 shares of our Series A-1 convertible preferred stock and warrants to purchase 2,228,573 shares of our common stock for an aggregate purchase price of $6.8 million.

In August 2013, in connection with the sale of the Series A-1 convertible preferred stock, we issued a warrant to purchase 680,588 shares of our common stock to the placement agent in such offering.

In May 2012, we issued and sold to investors at a purchase price of $0.75 per unit an aggregate of 1,600,000 shares of our Series A convertible preferred stock and warrants to purchase 400,000 shares of our common stock for an aggregate purchase price of $1.2 million.

In April 2012, we issued and sold to investors at a purchase price of $0.75 per unit an aggregate of 464,000 shares of our Series A convertible preferred stock and warrants to purchase 116,000 shares of our common stock for an aggregate purchase price of $348,000.

In April 2012, in connection with the sale of the Series A convertible preferred stock, we issued a warrant to purchase 3,530,559 shares of our common stock to the placement agent in such offerings.

In March 2012, we issued and sold to investors at a purchase price of $0.75 per unit an aggregate of 12,854,643 shares of our Series A convertible preferred stock and warrants to purchase 3,213,656 shares of our common stock for an aggregate purchase price of $9.6 million. We also issued 4,077,475 shares of our Series A convertible preferred stock and a warrant to purchase 1,019,368 shares of our common stock upon the conversion of the convertible demand promissory note issued in April 2011.

In February 2012, we issued and sold to investors at a purchase price of $0.75 per unit an aggregate of 12,120,273 shares of our Series A convertible preferred stock and warrants to purchase 3,030,066 shares of our common stock for an aggregate purchase price of $9.1 million.

In April 2011, we issued and sold 18,000,000 shares of our common stock, which included 3,000,000 shares of common stock subject to restrictions that ultimately lapsed in September 2011, as discussed in subsection (b) below, and an additional 400,000 shares of common stock were subsequently converted into restricted common stock with a three year vesting period, to investors, employees and advisors at a price of $0.001 per share for an aggregate purchase price of $18,000.

In April 2011, we issued a convertible demand promissory note to an investor in an initial principal amount of $500,000 and additional advances of $2.5 million were made under such note through November 2011.

No underwriters were involved in the foregoing sales of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of shares of our preferred stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

(b) Stock Option and Restricted Stock Grants

Since inception, we have (i) issued 3,000,000 shares of restricted common stock, at a purchase price of $0.001 per share, to an executive officer pursuant to the 2011 Stock Incentive Plan, (ii) granted stock options to purchase an aggregate of 5,987,375 shares of our common stock, with exercise prices ranging from $0.01 to $0.32 per share, to employees, directors and consultants pursuant to the 2011 Stock Incentive Plan and (iii) granted stock options to purchase an aggregate of 4,700,000 shares of our common stock, with an exercise price of $0.31 per share, to employees, directors and consultants outside of the 2011 Stock Incentive Plan. Of these options, none have been exercised.

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities described in sections (a) and (b) of Item 15 are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

Item 16. Exhibits and Financial Statement Schedules.

(a) The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

(b) No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Baltimore, State of Maryland, on this th day of , 2013.

CERECOR INC.

By: _____

Blake M. Paterson, M.D.
President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of Cerecor Inc., hereby severally constitute and appoint Dr. Blake M. Paterson, M.D., and Ms. Federica F. O'Brien, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and any other registration statement for the same offering pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
Blake M. Paterson, M.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	
Federica F. O'Brien	Chief Financial Officer (Principal Financial and Accounting Officer)	
Sol Barer, Ph.D.	Director	
Eugene A. Bauer, M.D.	Director	
Isaac Blech	Director	
John Catsimatidis	Director	
Magnus Persson, M.D., Ph.D.	Director	
Cary W. Sucoff	Director	

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement
3.1*	Certificate of Incorporation of Cerecor Inc., as currently in effect
3.2*	Form of Amended and Restated Certificate of Incorporation of Cerecor Inc. (to become effective upon the closing of this offering)
3.3*	Bylaws of Cerecor Inc., as currently in effect
3.4*	Form of Amended and Restated Bylaws of Cerecor Inc. (to become effective upon the closing of this offering)
4.1*	Amended and Restated Investors' Rights Agreement, dated as of August 23, 2013
4.2*	Form of Warrants to Purchase Shares of Common Stock.
4.3*	Common Stock Warrant, dated as of April 4, 2012, issued to Maxim Partners LLC.
4.4*	Common Stock Warrant, dated as of August 23, 2013, issued to Maxim Partners LLC.
5.1*	Opinion of Morgan, Lewis & Bockius LLP
10.1*	Exclusive Patent and Know-How License Agreement, effective as of March 19, 2013, by and between Essex Chemie AG and Cerecor Inc.
10.2*	Exclusive Patent and Know-How License Agreement, effective as of March 19, 2013, by and between Essex Chemie AG and Cerecor Inc.
10.3*+	Cerecor Inc. 2011 Stock Incentive Plan, as amended, including forms of Incentive Stock Option Agreement and Nonqualified Stock Option Agreements thereunder.
10.4*+	Offer Letter Agreement by and between Cerecor Inc. and Blake M. Paterson, dated as of April 28, 2011.
10.5*+	Offer Letter Agreement by and between Cerecor Inc. and John Kaiser, dated as of September 12, 2012.
10.6*+	Offer Letter Agreement by and between Cerecor Inc. and James Vornov, dated as of September 18, 2012.
10.7*+	Offer Letter Agreement by and between Cerecor Inc. and Federica F. O'Brien, dated as of April 1, 2013.
10.8*	Lease Agreement by and between Cerecor Inc. and PDL Pratt Associates, LLC, dated as of August 8, 2013.
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Morgan, Lewis and Bockius LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included in the signature page to this registration statement)

* To be filed by amendment.

\+ Management compensatory agreement.