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

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **January 27, 2017**

Cerecor Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation)	001-37590 (Commission File Number)	45-0705648 (IRS Employer Identification No.)
400 E. Pratt Street Suite 606 Baltimore, Maryland (Address of Principal Executive Offices)		21202 (Zip Code)

Registrant's Telephone Number, Including Area Code: **(410) 522-8707**

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01. Other
Events.**

On January 27, 2017, Cerecor Inc. (the "**Company**") entered into an Equity Distribution Agreement with Maxim Group LLC, as sales agent ("**Maxim**"), pursuant to which the Company may offer and sell, from time to time, through Maxim (the "**Offering**"), up to \$12,075,338 in shares of its common stock. In connection with the Offering, the Company is filing this Current Report on Form 8-K to update its risk factors previously disclosed in its periodic and other reports filed with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended. A copy of the updated risk factors is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy shares of the Company's common stock, nor shall there be any offer, solicitation or sale of these securities in any state or country in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or country. Any offers of the securities will be made only by means of a prospectus.

**Item 9.01. Financial Statements and
Exhibits.**

Exhibit No.	Description
99.1	Risk Factors.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cerecor Inc.

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

Date: January 30, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should carefully consider the risks and uncertainties described below together with all other information contained in or incorporated by reference in our other filings with the United States Securities and Exchange Commission, or the SEC. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might 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, as well as our initial public offering in October 2015 and our common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital is committed to purchase up to an aggregate of \$15.0 million of our shares of common stock over the 30-month term of the Purchase Agreement. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses in each period since our inception in 2011. We incurred net losses of \$10.5 million, \$16.1 million and \$13.0 million for the years ended December 31, 2015, 2014 and 2013, respectively, and \$14.8 million as of September 30, 2016. As of September 30, 2016, we had an accumulated deficit of \$68.4 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development program and from general and administrative costs associated with our operations.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek marketing approvals for, our product candidates. If we do not successfully develop and obtain marketing approval for our product candidates and effectively market and sell any product candidates that are approved, we may never generate product sales. Even if we do generate product sales, we may never achieve or sustain profitability on an annual basis. Furthermore, following our initial public offering in October 2015, we have incurred additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

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

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

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

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

We will require additional capital to finance the further advancement of our product candidates and to fund our operations, which may not be available to us on acceptable terms, or at all. Failure to obtain this necessary capital when needed will force us to delay, limit or terminate our product development efforts or other operations.

We do not currently have sufficient funds to further advance any of our product candidates, including our planned initiation of a Phase 2/3 clinical trial with CERC-501 as an adjunctive treatment of major depressive disorder, or MDD, and our plan to file an IND with the FDA for CERC-611 and to commence Phase 1 development in 2017. We will require additional capital to finance our operations and pursue any further development of our product candidates. Following the conclusion of our recent Phase 2 clinical trial for CERC-501 for smoking cessation, which failed to meet its primary efficacy endpoint, we plan to initiate a Phase 2/3 clinical trial for CERC-501 in 2017, subject to the availability of additional funding. We are assessing the results of our recent Phase 2 clinical trial for CERC-301 for MDD which failed to meet its primary efficacy endpoint but we believe suggested a potentially clinically meaningful treatment effect in the 20 mg dose, and will announce potential next steps at a later date. We plan to file an investigational new drug application, or an IND, with the FDA for CERC-611, subject to the availability of additional funding, and commence Phase 1 development in 2017 as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy.

As a research and development company, our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into clinical trials or obtain and advance additional product candidates. Circumstances may cause us to consume capital more rapidly than we currently anticipate. For example, as we move our product candidates through clinical trials, we may fail to meet our primary or secondary endpoints, which we recently reported had occurred for our Phase 2 clinical trials for CERC-301 and CERC-501, respectively, and previously had occurred for our first Phase 2 study for CERC-301, requiring us to complete more trials than originally expected or we may discover serious adverse side effects. Moreover, as we move our COMT inhibitor, or COMTi, product candidates, such as CERC-406, through preclinical studies and continue to evaluate the development plan for CERC-611, submit Investigational New Drug Applications, or INDs, and initiate clinical trials, we may produce adverse results requiring us to find new product candidates. Any of these events may increase our development costs more than we expect. We may need to raise additional funds or otherwise obtain funding through collaborations if we choose to initiate additional clinical trials for product candidates. In any event, we will require additional capital to obtain marketing approval for, and to commercialize, future product candidates.

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

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

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

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

If a lack of available capital results in our inability to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected. We had cash and cash equivalents of \$5.1 million as of December 31, 2016.

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

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

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

Our recurring operating losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. We have no current source of revenues to sustain our present activities, and we do not expect to generate revenues until, and unless, the FDA or other regulatory agencies approve our product candidates and we successfully commercialize any such product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our inability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change federal net operating loss carryforwards, or NOLs, and other pre-change federal tax attributes (such as research tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future and subsequent shifts in our stock ownership. State NOL carryforwards may be similarly or more stringently limited. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. We have not analyzed the historical or potential impact of our equity financings on beneficial ownership and therefore no determination has been made on whether our NOL carryforwards are subject to the limitations described above.

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

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

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

We commenced active operations in 2011. To date our operations have consisted of organizing and staffing our company, business planning, raising capital and developing our product candidates and platform. We have not yet demonstrated our ability to successfully develop any product candidate, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

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

Since inception, we have in-licensed each of our product candidates, including most recently CERC-611, and our COMTi platform. From time to time we may consider additional in-licensing of products and other strategic transactions, such as acquisitions of companies, asset purchases and out-licensing of product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including strategic partnerships, collaborations, joint ventures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business,

which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

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

Risks Related to Our Business and Industry

We are heavily dependent on the success of our product candidates, CERC-501, CERC-611 and potentially CERC-301. If we fail to obtain marketing approval for and commercialize any product candidates, or experience delays in doing so, our business will be materially harmed.

Subject to the availability of additional funding, we intend to invest a significant portion of our efforts and financial resources in the development of our product candidates CERC-501, CERC-611 and possibly CERC-301. To date we have not marketed, distributed or sold any products. Our ability to generate revenues is substantially dependent on the development and commercialization of CERC-301 and CERC-501. We recently announced that neither CERC-301 nor CERC-501 reached its primary efficacy endpoint in its respective Phase 2 clinical trial. We intend to continue to pursue development of CERC-501, but we are currently evaluating the data from our CERC-301 trial and we have not finalized our plans as to its further development. We also recently in-licensed CERC-611, which has not undergone any clinical testing to date, and we are planning to prepare and file an IND with the FDA for CERC-611 and thereafter commence clinical development as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy. If our clinical development for CERC-501 is successful, we plan to submit an NDA seeking approval to commercialize CERC-501 for adjunctive treatment of MDD. We cannot commercialize our product candidates prior to obtaining marketing approval from the FDA. Each of our product candidates is susceptible to the risks of failure inherent at any stage of drug development, including the appearance of unexpected adverse events, the failure to demonstrate efficacy and the FDA's determination that such candidate is not approvable. If we do not receive marketing approval for and commercialize any of our product candidates, we will not be able to generate product revenues in the foreseeable future, or at all.

If, following submission, our NDA for a product candidate is not accepted for substantive review or approved, the FDA may require that we conduct additional clinical or preclinical trials, manufacture additional validation batches or develop additional analytical test methods before it will reconsider our application for such product candidate. If the FDA requires additional studies or data, we would incur increased costs and delays in the

marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional required trials that we perform and complete to be sufficient.

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

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

We have invested a significant portion of our efforts and financial resources in the identification and preclinical and clinical development of product candidates. For example, a significant portion of our financial resources were dedicated to the development of FP01, which we no longer plan to develop. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on our ability to advance our preclinical product candidates, including CERC-611 and CERC-406, into clinical development and successfully complete preclinical testing of our clinical stage product candidates. The outcome of preclinical studies may not predict the success of clinical trials. Preclinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed in clinical development. Our inability to successfully complete preclinical development could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales.

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

Before obtaining required approvals from regulatory authorities for the sale of future product candidates, we alone, or with a partner, must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. For example, we recently announced neither the Phase 2 clinical trial for CERC-301 for MDD nor the Phase 2 clinical trial for CERC-501 for smoking cessation met its respective primary endpoint. Previously, the Clin301-201 study for CERC-301 failed to meet its primary endpoint and our discontinued product candidate FP01 failed to meet its primary endpoint in two Phase 2 clinical studies. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Our product candidates will require additional clinical and preclinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply on our own or from a third party, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales. We do not know whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates would be adversely impacted.

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

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

Events which may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching an agreement with or failure in obtaining authorization from the FDA, other regulatory authorities or institutional review boards, or IRBs, to commence or amend a clinical trial;
 - imposition of a clinical hold or trial termination following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities, or due to concerns about trial design, or a decision by the FDA, other regulatory authorities, IRBs or the company, or recommendation by a data safety monitoring board, to place the trial on hold or otherwise suspend or terminate clinical trials at any time for safety issues or for any other reason;
 - delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
 - deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
 - failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
 - failure to enter into agreements with third parties to obtain the results of clinical trials;
 - delays in the importation and manufacture of clinical supply;
 - delays in the testing, validation and delivery of the clinical supply of the product candidates to the clinical sites;
 - for clinical trials in selected subject populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected subjects;
 - delays in recruiting suitable subjects to participate in a trial;
 - delays in having subjects complete participation in a trial or return for post-treatment follow-up;
 - delays caused by subjects dropping out of a trial due to side effects or disease progression;
 - delays in adding new investigators and clinical trial sites;
 - withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
 - changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.
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Any inability by us or our partners to timely complete clinical development could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales. For example, the National Institutes of Health discontinued a Phase 2 trial for CERC-501 for treatment-resistant depression, which was funded by the National Institute of Mental Health, due to slow study progression.

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

Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit appropriate subjects to participate in testing our product candidates as well as completion of required follow-up periods. If subjects are unwilling to participate in our trials because of negative publicity from adverse events in the biotechnology industry or for other reasons, including competitive clinical trials for similar subject populations, the timeline for recruiting subjects, conducting trials and obtaining marketing approval of potential products may be delayed. For example, we have experienced delays in enrolling patients in our CERC-301 Phase 2 clinical trial, due in part we believe to the highly competitive environment for recruiting patients to clinical trials studying depression. In addition, we believe the decision by the National Institutes of Health to discontinue a Phase 2 trial for CERC-501 was due in part to difficulties experienced in enrolling patients into the trial.

Difficulty or delays in patient recruitment into our trials could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. Many factors affect subject enrollment, including:

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

There is significant competition for recruiting subjects in clinical trials for product candidates for the treatment of depression, substance use disorders and impaired executive function, and we or our partners may be unable to enroll the subjects we need to complete clinical trials on a timely basis or at all. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. If we are unable to enroll sufficient subjects in our clinical trials, if enrollment is slower than we anticipate, or if our clinical trials require more subjects than we anticipate, our clinical trials may be delayed or may not be completed. If we experience delays in our clinical trials, the commercial prospects of our product candidates will be harmed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

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

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

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

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

- our methodology, including our screening technology, may not successfully identify medically relevant potential product candidates;
 - our competitors may develop alternatives that render our product candidates obsolete;
 - we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable;
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- our product candidates may cause adverse effects in subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- our product candidates may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- our product candidates may not demonstrate a meaningful benefit to subjects;
- our potential collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product; and
- our reliance on third party clinical trials may cause us to be denied access to clinical results that may be significant to further clinical development.

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

We may not be successful in our efforts to leverage and expand our COMTi platform to build a pipeline of product candidates or to develop and commercialize our preclinical product candidates, CERC-406 and CERC-611.

An element of our strategy is to leverage and expand our COMTi platform to build a pipeline of product candidates for conditions with impairment of executive function, and to progress these product candidates through clinical development for the treatment of a variety of different types of diseases states involving impaired executive functioning. To date, we have selected a lead preclinical candidate for our COMTi platform, CERC-406, but CERC-406 or any other product candidates developed from our COMTi platform may not be safe or effective. In September 2016, we acquired exclusive worldwide rights to CERC-611, which is in preclinical development and we intend to develop as an adjunctive therapy for the treatment of partial-onset seizures, with or without secondarily generalized seizures, in patients with epilepsy. We will require additional capital to finance any further preclinical development of our COMTi product candidates, such as CERC-406, and to prepare and file an IND with the FDA for CERC-611 and thereafter commence clinical development, and such capital may not be available on attractive terms or at all. Further, our continued development of both the COMTi platform and CERC-611 will be dependent upon receiving positive preclinical and clinical data that, in our judgment, merits advancing such programs. Even if we are successful in continuing to build and expand our COMTi pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Similarly, even if the FDA approves our IND for CERC-611, there is no guarantee that we will be successful in our efforts to advance CERC-611 into clinical trials. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

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

The time required to obtain approval to market new drugs by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have

not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval. Moreover, the filing of an NDA requires a payment of a significant NDA user fee upon submission. The filing of an NDA for our product candidates may be delayed due to our lack of financial resources to pay such user fee.

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

- the FDA or comparable foreign regulatory authorities may disagree on the design or implementation of our clinical trials, including the methodology used in our trial, our chosen endpoints, our statistical analysis, or our proposed product indication. For instance, the FDA may find that the designs that we are utilizing in our planned Phase 2/3 clinical trial of CERC-501 do not support an adequate and well-controlled study. The FDA also may not agree with the various depression and other disease scales and evaluation tools that we may use in our clinical trials to assess the efficacy of our product candidates. Further, the FDA may not agree with our endpoints and/or indications selected for our trials;
 - the FDA or comparable foreign regulatory authorities may disagree with our development plans for our product candidates. For instance, at this time we have not yet discussed our development plans for CERC-501, CERC-611 or CERC-406 with the FDA. While we plan to discuss the development of these product candidates with the FDA, the FDA may not agree with our current development approach;
 - our failure to demonstrate to the satisfaction of the FDA or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
 - our clinical trials may fail to meet the level of statistical significance required for approval. For example, in a proof of concept study of CERC-301 conducted by the National Institute of Mental Health, CERC-301 failed to provide a significant improvement in subjects receiving the compound as compared to those receiving a placebo, as measured by the Montgomery-Asberg Depression Rating Scale, the primary assessment tool. Further, we recently announced that neither CERC-301 nor CERC-501 met the primary endpoint in its respective Phase 2 clinical trial, and previously our Clin301-201 Phase 2 study for CERC-301 failed to meet its primary endpoint;
 - we may fail to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
 - the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
 - data collected from clinical trials of our product candidates may be insufficient to support the submission and filing of an NDA, other submission or to obtain marketing approval. For example, the FDA may require additional studies to show that our product candidates are safe or effective;
 - we may fail to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
 - there may be changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.
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The FDA or comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, including more limited patient populations, may require that contraindications, warnings or precautions be included in the product labeling, including a black-boxed warning, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-market requirements, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

We have received a fast track product designation for CERC-301 for the treatment of MDD and we may seek a breakthrough therapy designation and priority review designation. For CERC-501 and CERC-611, or for certain of our other product candidates, if supported by the results of clinical trials, we may seek fast track product designation, breakthrough therapy designation and priority review designation. A fast track product designation is designed to facilitate the clinical development and expedite the review of drugs intended to treat a serious or life-threatening condition which demonstrate the potential to address an unmet medical need. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Priority review designation is intended to speed the FDA marketing application review timeframe for drugs that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. For drugs and biologics that have been designated as fast track products or breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development. Sponsors of drugs designated as fast track products or breakthrough therapies may also be able to submit marketing applications on a rolling basis, meaning that the FDA may review portions of a marketing application before the sponsor submits the complete application to the FDA, as long as the sponsor pays the user fee upon submission of the first portion of the marketing application. For products that receive a priority review designation, the FDA's marketing application review goal is shortened to six months, as opposed to ten months under standard review. This review goal is based on the date the FDA accepts the marketing application for review, which typically adds approximately two months to the timeline for review and decision from the date of submission.

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

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

The FDA grants product sponsors certain periods of regulatory exclusivity, during which the agency may not approve, and in certain instances, may not accept, certain marketing applications for competing drugs. For example, product sponsors may be eligible for five years of exclusivity from the date of approval of a new chemical entity, seven years of exclusivity for drugs that are designated to be orphan drugs, and/or a six-month period of exclusivity added to any existing exclusivity period or patent life for the submission of FDA requested pediatric data. While we intend to apply for all periods of market exclusivity that we may be eligible for, there is no guarantee that we will receive all such periods of market exclusivity. Additionally, under certain circumstances, the FDA may revoke the period of market exclusivity. Thus, there is no guarantee that we will be able to maintain a period of market exclusivity, even if granted. Moreover, we have not sought to obtain orphan drug designation for any of our product candidates, which the FDA must first grant to be eligible for orphan drug exclusivity, but may if we determine that we may be eligible. In the case of orphan designation, other benefits, such as tax credits and exemption from user fees may be available. If we are not able to obtain or maintain orphan drug designation or any period of market exclusivity to which we may be entitled, we will be materially harmed, as we will potentially be subject to greater market competition and may lose the benefits associated with programs.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authority. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Although CERC-301 was generally well tolerated in our recently completed Phase 2 clinical trial for MDD, with no serious adverse events reported and no discontinuations due to adverse events, some adverse events were reported. The most commonly reported adverse events in the trial were increases in blood pressure, dizziness, somnolence and paresthesia. Similarly, although in our previously completed Phase 2 clinical study, Clin301-201, CERC-301 was generally well tolerated, there were rates of adverse events similar to that of placebo. The most common treatment emergent adverse events were nervous system disorders, occurring in 25.9% and 26.9%, respectively, of subjects in the two active treatment sequences compared to 22.4% of subjects who received placebo during the entire study. Of the nervous system treatment emergent adverse events, dizziness was most common, occurring in 18.5% and 7.7%, respectively, of subjects in the two active treatment sequences compared to 2.0% of subjects who received placebo during the entire study. Four serious adverse events in three subjects were reported during the conduct of the study, two in a subject randomized to placebo (suicide attempt; alcoholism) and two in subjects that received CERC-301 (worsening depression with psychotic features and unstable angina). Overall, the adverse events observed in both our most recent and prior studies were generally consistent with the prior clinical trials conducted for CERC-301, despite having administered an increased dose of CERC-301 in our most recent study. Although CERC-501 was also generally well tolerated in our recently completed Phase 2 clinical trial for smoking cessation, with no serious adverse events reported and no discontinuations due to adverse events, some adverse events were reported. The most commonly reported adverse events, over 5% and greater than placebo in the study, were diarrhea and decreased appetite.

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

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

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

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

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

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

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

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

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials,

the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain marketing approval from the relevant regulatory agencies. Additional delays may result if the FDA, an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for fewer or more limited indications than requested, may impose significant limitations in the form of narrow indications, warnings, including black-box warnings, precautions or contra-indications with respect to conditions of use or may grant approval subject to the performance of costly post-marketing clinical trials or other post-marketing requirements, including a REMS. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. For instance, in 2007, the FDA requested that makers of all antidepressant medications update an existing black-box warning about an increased risk of suicidal thought and behavior. Our drugs, if approved, may be required to carry warnings comparable to this and other class-wide warnings. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

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

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

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

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

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

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

civil and criminal settlements, such as settlements regarding certain sales practices promoting off-label drug uses involving fines that are as much as \$3.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There are numerous currently approved therapies for treating depression and, consequently, competition in the depression market is intense. Many of these approved drugs are well established therapies or products and are widely accepted by physicians, patients and third party payors. Some of these drugs are branded and subject to patent protection and non-patent regulatory exclusivity, and others are available on a generic basis. For example, CERC 301 would compete with drugs used as adjunctive therapies for the treatment of MDD such as Abilify, marketed by Otsuka America Pharmaceutical, Inc.; Seroquel XR, marketed by AstraZeneca Pharmaceuticals LP, or AstraZeneca; and bupropion, a generic drug. In addition, to our knowledge, there are five competitive rapid onset antidepressant or anti-suicide programs in development: esketamine, which is in Phase 3 development by Johnson & Johnson, or J&J, and is being developed to be administered as a nasal spray; AZD8108, which is in Phase 1 development by AstraZeneca and is being developed to be administered orally; Rapastinel, which has completed Phase 2 development by Allergan Plc., or Allergan, which is being developed to be administered intravenously; NRX 1074 by Allergan has completed a single intravenously administered dose Phase 2 study, which, along with oral and intravenous Phase 1 pharmacokinetic, or PK, findings, will be used to select an oral dose for a repeat-dose Phase 2 study; AV-101, an oral prodrug of 7-chlorokynurenic acid, is in Phase 2 development by VistaGen Therapeutics; and ALKS-5461, which is in Phase 3 development by Alkermes plc, or Alkermes, and is being developed to be administered orally as an adjunctive therapy and has shown signals of rapid onset as an adjunctive therapy. With respect to CERC-501, to our knowledge, there are no approved pharmacologic treatments for co-occurring disorders, however, there are two competitive programs in development: ALKS 5461, which is believed to be acting as a functional KOR antagonist that is now in Phase 3 development for MDD as an adjunctive in patients who have no more than two inadequate responses to antidepressant therapy and LY2940094, which has completed two Phase 2 studies by Eli Lilly and Company, or Lilly, and is being developed for the treatment of both

MDD and alcohol dependence. CERC-611 would compete with the non-selective AMPA receptor antagonist, Fycompa®, marketed by Eisai Inc.

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

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

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

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

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

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
 - the claims we may make for our product candidates based on the approved label or any restrictions placed upon our marketing and distribution of our product candidates;
 - the time it takes for our product candidates to complete clinical development and receive marketing approval;
 - how quickly and effectively we alone, or with a partner, can market and launch any of our product candidates that receive marketing approval;
 - the ability to commercialize any of our product candidates that receive marketing approval;
 - the price of our products, including in comparison to branded or generic competitors;
 - the ability to collaborate with others in the development and commercialization of new products;
 - whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
 - the ability to establish, maintain and protect intellectual property rights related to our product candidates;
 - the entry of generic versions of our products onto the market;
 - the number of products in the same therapeutic class as our product candidates;
 - the ability to secure favorable managed care formulary positions, including federal healthcare program formularies;
 - the ability to manufacture commercial quantities of any of our product candidates that receive marketing approval; and
 - acceptance of any of our product candidates that receive marketing approval by physicians and other healthcare providers.
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If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, third-party payors and patients, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

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

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products will be available from government authorities (such as Medicare and Medicaid), private health insurers, health maintenance organizations and other entities. These third-party payors determine which medications they will cover and establish reimbursement levels, and increasingly attempt to control costs by limiting coverage and the amount of reimbursement for particular medications. Several third-party payors are requiring that drug companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for drugs. In addition, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

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

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

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

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

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

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

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

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

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

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

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for outpatient prescription drug purchases through pharmacies, by the elderly by establishing Medicare Part D and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that Medicare will cover in any therapeutic class under the new Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and

reimbursement rate that we receive for any of our approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, the Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and other medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Therefore, any reduction in reimbursement that results from healthcare reform impacting government programs may result in a similar reduction in payments from private payors.

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

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

Significant uncertainty exists regarding the effect of the Affordable Care Act, particularly in light of the pending change in the Administration following the recent elections and campaign pledges to repeal or reform the Affordable Care Act. However, if the new law is maintained in its current form, it appears likely that it would continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in

spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013.

We expect that the Affordable Care Act, as well as other state and federal healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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

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

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

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

We currently hold \$10.0 million in clinical trial liability insurance coverage, which may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
 - the civil federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. Civil False Claims Act liability may be imposed for Medicare or Medicaid overpayments,
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for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act;

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

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

If our operations are found to be in violation of any of these laws or any other governmental regulations or requirements that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, restitution exclusion from government funded healthcare programs, such as Medicare and Medicaid, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts, contractual damages, the curtailment or restructuring of our operations and other consequences. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Moreover, availability of any federal grant funds which we may receive or for which we may apply is subject to federal appropriations law. Grant funding may also be withdrawn or denied for other reasons. For instance, the National Institutes of Mental Health, or NIMH, decided to discontinue the funding of a Phase 1 study of CERC-501 that was to be conducted by a third party as NIMH decided the study would be unlikely to provide new information beyond what a NIMH funded Phase 2 study, conducted by the same third party, would provide. Similarly, in January 2016 NIMH decided to discontinue the funding of a Phase 2 study of CERC-501 for treatment-resistant depression that was to be conducted by the National Institutes of Health and sponsored by Massachusetts General Hospital because of slow study progression.

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

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on Uli Hacksell, Ph.D., our Chief Executive Officer and President and Chairman of our board of directors. The loss of the services of Dr. Hacksell could impede, delay or prevent the development of our product candidates and could negatively impact our ability to successfully implement our business plan. If we lose the

services of Dr. Hacksell, we may not be able to find a suitable replacement on a timely basis, or at all, and our business would likely be harmed as a result. We do not maintain a “key man” insurance policy on Dr. Hacksell’s life or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies.

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

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

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

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

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are

considering. We have adopted an Insider Trading Policy, but despite the adoption of such policy, we may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

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

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

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

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

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
 - the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the clinical benefits of our products to achieve market acceptance;
 - the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
 - the costs associated with training sales personnel on legal compliance matters and monitoring their actions;
 - liability for sales personnel failing to comply with the applicable legal requirements;
and
 - unforeseen costs and expenses associated with creating an independent sales and marketing organization.
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Where and when appropriate, we may elect to utilize contract sales forces or strategic partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. Such third parties may also not comply with the applicable regulatory requirements, which could potentially expose us to regulatory and legal enforcement actions.

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

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

Our CROs and clinical trial sites are not our employees, and, except for remedies available to us under our agreements with such CROs and clinical trial sites, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. These CROs and clinical trial sites may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If CROs or clinical trial sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain marketing approval for or successfully commercialize our product candidates or we may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the

claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

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

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

Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to develop, manufacture, market and sell our product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates or face other penalties under these agreements. We have entered into exclusive license agreements with Merck & Co., Inc. and its affiliates, or Merck, pursuant to which Merck has granted us rights to the compounds used in CERC-301 and the COMTi platform, including CERC-406. We have also entered into exclusive license agreements with Lilly pursuant to which Lilly has granted us rights to the compounds used in CERC-501, as well as an exclusive license, development and commercialization agreement with Lilly pursuant to which we received exclusive global rights to develop and commercialize CERC-611. If we fail to comply with the obligations under these agreements, including payment terms, Merck and Lilly may have the right to terminate any of these agreements, in which event we may not be able to develop, market or sell CERC-301, CERC-501, CERC-611 or any product candidate developed from the COMTi platform, including CERC-406. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the United States Patent and Trademark Office, or USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within

prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

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

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

Third party preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related

technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

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

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

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In addition, we may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement to each party who in fact develops intellectual property that we regard as our own. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims.

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

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

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Though we seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, as well as by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no

right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or

collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

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

Risks Related to our Stock

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

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

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

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

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

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

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

The market price of our shares of our common stock has been highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, you may not be able to sell your shares of our common stock. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein, these factors that could negatively affect or result in fluctuations in the market price of shares of our common stock include:

- the development status of our product candidates, and when any of our product candidates receive marketing approval;
 - our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
 - our failure to commercialize our product candidates, if approved;
 - the success of competitive products or technologies;
 - regulatory actions with respect to our products or our competitors’ products;
 - actual or anticipated changes in our growth rate relative to our competitors;
 - announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
 - results of preclinical studies and clinical trials of our product candidates or those of our competitors;
 - regulatory or legal developments in the United States and other countries;
 - developments or disputes concerning patent applications, issued patents or other proprietary rights;
 - the recruitment or departure of key personnel;
 - the level of expenses related to any of our product candidates or clinical development programs;
 - the results of our efforts to discover, develop, in-license or acquire additional product candidates or products;
 - actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
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- the performance of third parties on whom we rely to manufacture our products and product candidates, supply API and conduct our clinical trials, including their ability to comply with regulatory requirements;
 - variations in our financial results or those of companies that are perceived to be similar to us;
 - variations in the level of expenses related to our product candidates or preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our contract research organizations and clinical trial sites;
 - fluctuations in the valuation of companies perceived by investors to be comparable to us;
 - warrant or share price and volume fluctuations attributable to inconsistent trading volume levels of our warrants or shares;
 - announcement or expectation of additional financing efforts;
 - sales of our warrants or shares of our common stock by us, our insiders or our other security holders;
 - changes in the structure of healthcare payment systems;
 - changes in operating performance and stock market valuations of other pharmaceutical companies;
 - market conditions in the pharmaceutical and biotechnology sectors;
 - our execution of collaborative, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
 - the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC and announcements relating to litigation or other disputes, strategic transactions or intellectual property impacting us or our business;
 - the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
 - changes in financial estimates by any securities analysts who follow our warrants or shares of common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our warrants or shares of common stock;
 - ratings downgrades by any securities analysts who follow our warrants or shares of common stock;
 - the development and sustainability of an active trading market for our warrants or shares of common stock;
 - future sales of our warrants or shares of common stock by our officers, directors and significant stockholders;
 - other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
 - changes in accounting principles;
 - and
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- general economic, industry and market conditions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have determined to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an “emerging growth company.” For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company,” which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an “emerging growth company,” we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers,

that we would otherwise have been required to provide in filings we make with the SEC which may make it more difficult for investors and securities analysts to evaluate our company. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our warrants or shares of common stock less attractive as a result, there may be a less active trading market for our warrants or shares of common stock, and the securities prices may be more volatile and may decline.

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

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

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

The trading market for our warrants and shares of common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited, and may not sustain, research coverage by securities and industry analysts. If we do not sustain coverage of our company, the trading price for our warrants and shares of common stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our warrants and shares of common stock or publishes inaccurate or unfavorable research about our business, our securities prices would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our warrants and shares of common stock could decrease, which could cause our securities prices and trading volume to decline.

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC, The NASDAQ Capital Market and other applicable securities rules and regulations imposed on public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Because these rules and regulations are often subject to varying interpretations, it is difficult to accurately estimate or predict the amount or timing of these additional costs. Further, the lack of specificity of many of the rules and regulations may result in an application in practice that may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

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

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

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

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

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

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

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

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

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

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

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

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which may

discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our securities.