VistaGen Therapeutics, Inc.
Form 424B3
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Prospectus

Dated August 31, 2015

3,992,479 Shares of Common Stock

VISTAGEN THERAPEUTICS, INC.

We are registering for resale up to 3,992,479 shares of common stock, $0.001 per share, of VistaGen Therapeutics, Inc. ("we," "us," or the "Company"), held by the selling stockholders listed beginning on page 115 of this prospectus ("Selling Stockholders"). All of the shares being registered are being or may be offered for resale by the Selling Stockholders. The shares of common stock registered for potential resale by the selling stockholders under this prospectus include:

- up to 2,951,688 shares of common stock issuable upon conversion of shares of Series B 10% Convertible Preferred Stock ("Series B Preferred") issued in a series of self-placed private placement transactions, the first of which was consummated on May 12, 2015 (the "Private Placements"); and

- up to 1,040,791 shares of common stock issuable upon exercise of warrants to purchase common stock ("Warrants") issued in connection with the Private Placements.

We will not receive any proceeds from the resale of any shares of common stock by the Selling Stockholders under this prospectus. However, if Warrants are exercised by the Selling Stockholders who hold them, we will receive the exercise price of any such Warrant exercises. We will pay the expenses of registering the shares of common stock for resale by the Selling Stockholders under this prospectus. See "Selling Stockholders" beginning on page 115 of this prospectus for a list of the Selling Stockholders.

The shares of common stock are being registered to provide the Selling Stockholders the opportunity to resell the shares from time to time, in amounts and at prices and on terms they may determine at the time of the offering. The Selling Stockholders may resell the shares of our common stock covered by this prospectus in a number of different ways and at prevailing market prices or privately negotiated transactions. We provide more information about how the Selling Stockholders may resell their shares in the section entitled "Plan of Distribution" beginning on page 118 of this prospectus.

Our common stock is quoted on the OTCQB under the symbol "VSTA." The last reported sale price of our common stock on August 28, 2015 was $11.00 per share.

No underwriter or other person has been engaged to facilitate the resale of shares of common stock or exercise of Warrants by the Selling Stockholders under this prospectus.

You should rely only on the information contained in this prospectus. We have not, and the Selling Stockholders have not, authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. If anyone provides you with different information, you should not rely on

it. We are not, and the Selling Stockholders are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 3 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is August 31, 2015.

VistaGen Therapeutics, Inc.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with additional information or information different from that contained in this prospectus. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

We own or have rights to use a number of common law trademarks and trade names that we use in connection with our business, including VistaGen Therapeutics, Inc., VistaGen, our logo, Better Cells Lead to Better Medicine, Human Clinical Trials in a Test Tube, CardioSafe 3D and LiverSafe 3D. Solely for convenience, the trademarks and trade names referred to in certain portions of this prospectus may have been included without the TM symbol, but any such references are not intended to indicate in any way that we will not assert to the fullest extent under applicable law our rights to use those trademarks and trade names. All other trademarks, service marks and trade names referred to in this prospectus, if any, are, to our knowledge, the property of their respective owners.

Unless the context otherwise requires, the words “VistaGen Therapeutics, Inc.” “VistaGen,” “we,” “the Company,” “us” and “
refer to VistaGen Therapeutics, Inc., a Nevada corporation. “VistaGen California” refers to VistaGen Therapeutics, Inc.,
a California corporation and our wholly owned subsidiary.

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FORWARD-LOOKING STATEMENTS

This prospectus, including the information incorporated by reference, contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. The use of any statements containing the words "intend," "believe," "estimate," "project," "expect," "anticipate," "plan," "should" or similar expressions are intended to ider statement. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, changes in demand for our products and services, changes in the level of operating expenses, our ability to execute our business and operating plan, changes in general economic conditions that impact government spending, regulatory issues, dependence on third party suppliers, and other risks detailed in this prospectus under the heading "Risk Factors" and in our periodic report filings with the Securities and Exchange Commission (the "SEC").

Forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Forward-looking statements speak only as of the date they are made, and we assume no duty to and do not undertake to update forward-looking statements. These forward-looking statements may not meet the safe harbor for forward-looking statements pursuant to Sections 21E or 27A of the Securities Act. Actual results could differ materially from those anticipated in forward-looking statements and future results could differ materially from historical performance.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all the information you should consider before buying our common stock. You should read the following summary together with the more detailed information appearing in this prospectus, including our Consolidated Financial Statements for the years ended March 31, 2015 and 2014, and the Condensed Consolidated Financial Statements for the three months ended June 30, 2015 and 2014, and related notes thereto, as well as our risk factors beginning on page 3, before deciding whether to purchase shares of our common stock.

Overview

We are a clinical-stage biopharmaceutical company committed to developing and commercializing innovative product candidates for patients with depression, other diseases and various disorders related to the central nervous system ("CNS"), as well as cancer.

More than one billion people worldwide suffer from CNS disorders. Recently, the economic burden of these disorders was estimated at $2.0 trillion in the U.S. and European Union alone, a figure that is expected to triple by 2030. The World Health Organization estimates that 350 million people worldwide are affected by depression. According to the U.S. National Institutes of Health ("NIH"), major depression is one of the most common mental disorders in the U.S. In 2012, the NIH estimated 16 million adults aged 18 or older in the U.S. had at least one major depressive episode. This represented approximately 6.7 percent of all U.S. adults.

Our lead product candidate, AV-101, is an orally available small molecule prodrug in Phase 2 clinical development for Major Depressive Disorder ("MDD"). AV-101's mechanism of action ("MOA"), as an N-methyl-D-aspartate receptor ("NMDAR") antagonist binding selectively at the glycine-binding ("GlyB") co-agonist site of the NMDAR, is fundamentally different from all antidepressants currently approved by the U.S. Food and Drug Administration ("FDA"). In four preclinical studies utilizing well-validated animal models of depression, AV-101 was shown to induce fast-acting, dose-dependent, persistent and statistically significant antidepressant-like responses, following a single treatment, which was equivalent to responses seen with a control single sub-anesthetic dose of ketamine (sometimes used by clinicians off-label to treat MDD and suicidal behavior). In the same studies, fluoxetine (Prozac) did not induce rapid onset antidepressant-like responses. Preclinical studies also support the hypothesis that AV-101 has potential to treat several additional CNS disorders, including chronic neuropathic pain, epilepsy and neurodegenerative diseases, such as Parkinson's disease and Huntington's disease where modulation of the NMDAR may have therapeutic benefit.

Following two successful randomized, double-blind, placebo-controlled Phase 1 safety studies funded by the NIH, in February 2015, we entered into a Cooperative Research and Development Agreement ("CRADA") with the U.S. National Institute of Mental Health ("NIMH"), part of the NIH. Under the CRADA, we will collaborate with the NIMH on the initial Phase 2 clinical study of AV-101 in subjects with treatment-resistant MDD. Pursuant to the CRADA, the study will be conducted at the NIMH and be fully funded by the NIMH. It is contemplated that this clinical study will begin in Fall 2015 under the direction of Dr. Carlos Zarate, Jr., the NIMH's Chief of Experimental Therapeutics & Pathophysiology Branch and of the Section on Neurobiology and Treatment of Mood and Anxiety Disorders.

In addition to developing AV-101 for MDD and other CNS indications, we are applying our stem cell technology for drug rescue programs intended to identify and develop proprietary new chemical entities ("NCEs") for our internal drug candidate pipeline. Drug rescue involves (1) using our customized in vitro bioassay systems to predict potential heart and liver toxicity of NCEs, (2) leveraging prior investments by pharmaceutical companies and others related to screening large-scale compound libraries, optimizing and testing for efficacy NCEs that were terminated before FDA approval due to heart or liver toxicity and are now available in the public domain, and (3) applying modern medicinal

chemistry to produce safer NCEs for our internal development pipeline. Our CardioSafe 3D™ bioassay system uses our human pluripotent stem cell ("hPSC")-derived cardiomyocytes, or human heart cells. We believe CardioSafe 3D is more comprehensive and clinically predictive than the hERG assay, which is currently the only in vitro cardiac safety assay required by FDA guidelines. We use our hPSC-derived hepatocytes, or human liver cells, in our LiverSafe 3D™ bioassay system to predict potential liver toxicity of NCEs, including potential drug metabolism issues and adverse drug-drug interactions. CardioSafe 3D and LiverSafe 3D offer a new paradigm for evaluating and predicting potential heart and liver toxicity of NCEs, including drug rescue NCEs, early in the development process, long before costly, high risk animal studies and human clinical trials. We intend to develop internally for our pipeline each lead drug rescue NCE we produce.

THE OFFERING

Securities Offered by the Selling Stockholders	3,992,479 shares of common stock.
Common Stock Outstanding as of August 24, 2015	1,594,461 shares.
Use of Proceeds	We will not receive any of the proceeds of the shares of common stock which may be offered for resale by the Selling Stockholders. If Warrants held by certain of which may be the Selling Stockholders are exercised, we will receive the exercise proceeds from such exercises. The shares of common stock that may be resold by the Selling Stockholders under this prospectus are issuable upon the conversion of securities sold by us to the Selling Stockholders in a series of self-placed private placement transactions, or upon future exercise of Warrants.
Risk Factors	Prior to making an investment decision, you should carefully consider all of the information in this prospectus and, in particular, you should evaluate the risk factors set forth under the caption "Risk Factors" beginning on page 3.
Trading Symbol	VSTA

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Prospectus before investing in our securities. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and/or operating results. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend heavily on the success of AV-101. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize AV-101, or any product candidate.

We currently have no drug products for sale and may never be able to develop and commercialize marketable drug products. Our business depends heavily on the successful non-clinical and clinical development, regulatory approval and commercialization of AV-101 for depression, including Major Depressive Disorder ("MDD"), and various other diseases and disorders involving the central nervous system ("CNS"), as well as our ability to produce, develop and commercialize new chemical entities ("NCEs") from our drug rescue programs. AV-101 will require substantial additional Phase 2 and Phase 3 clinical development, testing and regulatory approval before we are permitted to commence its commercialization. Each drug rescue NCE will require substantial non-clinical development, all phases of clinical development, and regulatory approval before we are permitted to commence its commercialization. The non-clinical studies and clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through non-clinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our non-clinical studies or clinical trials. This process can take many years and may also include post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond the proceeds we have raised to date. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the U.S. Food and Drug Administration, or FDA, regulatory approval process and will be commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our non-clinical studies and clinical trials, we cannot assure you that AV-101 or any other product candidate will be successfully developed or commercialized.

We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application, or an NDA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We recently received FDA clearance to initiate the initial Phase 2 clinical trial involving AV-101, to study its safety, tolerability and efficacy in patients with MDD. If our Phase 2 clinical trial of AV-101 is successful, we expect the FDA to require us to complete at least one additional Phase 2 clinical trial and at least one pivotal Phase 3 clinical trial in order to submit an NDA for AV-101 as a treatment for MDD. However, the FDA may require that we conduct more than one additional Phase 2 clinical study and more than one Phase 3 pivotal trial of AV-101 before we can submit an NDA. The FDA may also require that we conduct additional toxicity studies and additional non-clinical studies before submitting an NDA for AV-101.

Obtaining FDA approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of AV-101 or any of our product candidates for many reasons, including, among others:

- we may not be able to demonstrate that the product candidate is safe and effective in treating a human disease or disorder, to the satisfaction of the FDA;

- the results of our non-clinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;

- the FDA may disagree with the number, design, size, conduct or implementation of our non-clinical studies and clinical trials;

- the FDA may require that we conduct additional non-clinical studies and clinical trials;

- the FDA or the applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our product candidates;

- the contract research organizations, or CROs, that we retain to conduct our non-clinical studies and clinical trials may take actions outside of our control that materially adversely impact our non-clinical studies and clinical trials;

- the FDA may find the data from non-clinical studies and clinical trials insufficient to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;

- the FDA may disagree with our interpretation of data from our non-clinical studies and clinical trials;

- the FDA may not accept data generated at our non-clinical studies and clinical trial sites;

- if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional non-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;

- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party contract manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or cGMPs; or

- the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

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Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market AV-101 or any other product candidate we may develop, including drug rescue NCEs. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We intend to seek FDA Fast Track designation for AV-101, and we may do so for other product candidates as well. If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for the FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe AV-101 and other product candidates are eligible for this designation, we cannot be sure that the review or approval will compare to conventional FDA procedures. Even if granted, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development programs.

The number of patients suffering from MDD has not been established with precision. If the actual number of patients with MDD is smaller than we anticipate, we may encounter difficulties in enrolling patients in our AV-101 clinical trials, including our impending NIH-funded Phase 2 clinical study of AV-101 in MDD, thereby delaying or preventing clinical development. Further, if AV-101 is approved for treatment of MDD, and the market for this indication is smaller than we anticipate, our ability to achieve profitability could be limited.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of AV-101 and other product candidates may not be predictive of the results of later-stage clinical trials. AV-101 or other product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This drug candidate development risk is heightened by any changes in planned clinical trials compared to completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for later stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

For example, the results of planned clinical trials may be adversely affected if we or our collaborator seek to optimize and scale-up production of a product candidate. In such case, we will need to demonstrate comparability between the newly manufactured drug substance and/or drug product relative to the previously manufactured drug substance and/or drug product. Demonstrating comparability may cause us to incur additional costs or delay initiation or completion of our clinical trials, including the need to initiate a dose escalation study and, if unsuccessful, could require us to complete additional preclinical or clinical studies of our product candidates.

If serious adverse events or other undesirable side effects are identified during the use of AV-101 in investigator-sponsored trials, it may adversely effect our development of AV-101 for MDD and other CNS indications.

AV-101 will be tested in an NIH investigator sponsored Phase 2 clinical trial for the treatment of MDD and may be subjected to testing in the future for other CNS indications in additional investigator sponsored clinical trials. If serious adverse events or other undesirable side effects, or unexpected characteristics of AV-101 are observed in investigator sponsored clinical trials of AV-101 or our clinical trials, it may adversely affect or delay our clinical development of AV-101, and the occurrence of these events would have a material adverse effect on our business.

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Positive results from early non-clinical studies and clinical trials of AV-101 or other product candidates are not necessarily predictive of the results of later non-clinical studies and clinical trials of such product candidates. If we cannot replicate the positive results from our earlier non-clinical studies and clinical trials of AV-101 or other product candidates in our later non-clinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Positive results from non-clinical studies of our product candidates, and any positive results we may obtain from early clinical trials of our product candidates, may not necessarily be predictive of the results from required later non-clinical studies and clinical trials. Similarly, even if we are able to complete our planned non-clinical studies or clinical trials of our product candidates according to our current development timeline, the positive results from our non-clinical studies and clinical trials of our product candidates may not be replicated in subsequent non-clinical studies or clinical trial results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, non-clinical findings made while clinical trials were underway or safety or efficacy observations made in non-clinical studies and clinical trials, including previously unreported adverse events. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in non-clinical studies and clinical trials nonetheless failed to obtain FDA approval. We have not yet completed any Phase 2 clinical trial for AV-101, and if we fail to produce positive results in our NIH-sponsored Phase 2 clinical trial of AV-101 in MDD, the development timeline and regulatory approval and commercialization prospects for AV-101 and, correspondingly, our business and financial prospects, would be materially adversely affected.

Failures or delays in the commencement or completion of our planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

We and the NIH are preparing to commence an NIH-funded Phase 2 clinical trial of AV-101 as a treatment for MDD. We will need to complete at least two additional large clinical trials prior to the submission of an NDA for AV-101 as a treatment for MDD. Successful completion of our clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of AV-101 for MDD and any other product candidates we may develop. We do not know whether the NIH-funded Phase 2 study of AV-101 or any of our future-planned clinical trials will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA may deny permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or may place a clinical trial on hold;

- delays in filing or receiving approvals of additional INDs that may be required;

- negative results from our ongoing non-clinical studies;

- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;

- difficulties obtaining Institutional Review Board, or IRB, approval to conduct a clinical trial at a prospective site or sites;

- challenges in recruiting and enrolling patients to participate in clinical trials, including the proximity of patients to trial sites;

- eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;

- severe or unexpected drug-related side effects experienced by patients in a clinical trial;

- delays in validating any endpoints utilized in a clinical trial;

- the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;

- reports from non-clinical or clinical testing of other CNS therapies that raise safety or efficacy concerns; and

- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues or loss of interest.

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Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board, or DSMB, overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues, including any that could be identified in our ongoing non-clinical carcinogenicity studies, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue clinical trials.

Changes in regulatory requirements, FDA guidance or unanticipated events during our non-clinical studies and clinical trials of our product candidates may occur, which may result in changes to non-clinical studies and clinical trial protocols or additional non-clinical studies and clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, FDA guidance or unanticipated events during our non-clinical studies and clinical trials may force us to amend non-clinical studies and clinical trial protocols or the FDA may impose additional non-clinical studies and clinical trial requirements. Amendments or changes to our clinical trial protocols would require resubmission to the FDA and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of clinical trials. Similarly, amendments to our non-clinical studies may adversely impact the cost, timing, or successful completion of those non-clinical studies. If we experience delays completing, or if we terminate, any of our non-clinical studies or clinical trials, or if we are required to conduct additional non-clinical studies or clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenue will be delayed.

We rely, and expect that we will continue to rely, on third parties to conduct any clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations, or CROs, to conduct clinical trials on our product candidates. We enter into agreements with third-party CROs to provide monitors for and to manage data for our clinical trials. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;

- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or