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Filed Pursuant to Rule 424(b)(3)
Registration No. 333-189935

PROSPECTUS

$70,000,000

coronado BIOSCIENCES

Common Stock

In accordance with the terms of the At Market Issuance Sales Agreement entered into with MLV & Co. LLC, or MLV, dated April 29, 2013, as amended on July 12, 2013, which we refer to as the sales agreement, we may offer and sell shares of our common stock, $0.001 par value per share, having an aggregate offering price of up to $70,000,000 from time to time through MLV, acting as agent.

Our common stock is traded on The NASDAQ Capital Market under the symbol "CNDO." The last reported sale price of our common stock on August 16, 2013 was $7.73 per share.

Sales of our common stock, if any, under this prospectus will be made by any method permitted that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, including by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by MLV and us. MLV will act as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

MLV will be entitled to compensation at a commission rate of up to 3% of the gross sales price per share sold. In connection with the sale of the common stock on our behalf, MLV may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended and the compensation of MLV may be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to MLV with respect to certain liabilities, including liabilities under the Securities Act of 1933, as amended.

Investing in these securities involves a high degree of risk. Before buying shares of our common stock, you should carefully consider the risk factors described in "Risk Factors" beginning on page SA-5 of this prospectus and in the documents incorporated by reference into this prospectus and any free writing prospectus that we have authorized for use in connection with this offering.

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

MLV & Co.

The date of this prospectus is August 20, 2013

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ABOUT THIS PROSPECTUS

This prospectus relates to the offering of our common stock. Before buying any of the common stock that we are offering, we urge you to carefully read this prospectus, together with the information incorporated by reference as described under the heading "Where You Can Find Additional Information About Us" and "Incorporation of Certain Documents by Reference." These documents contain important information that you should consider when making your investment decision.

This prospectus describes the specific terms of the common stock we are offering and also adds to and updates information contained in the documents incorporated by reference into this prospectus. To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference in this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference into this prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in or incorporated by reference in this prospectus and any free writing prospectus that we may authorize for use in connection with this offering. We have not, and MLV has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and MLV is not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information appearing in this prospectus, the documents incorporated by reference in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus, the documents incorporated by reference in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision.

Unless otherwise indicated in this prospectus or the context otherwise requires, all references to "we," "us," "our," "the Company," and "Coronado" refer to Coronado Biosciences, Inc. and its subsidiary.

PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus, including the information incorporated by reference into this prospectus, and the information referred to under the heading "Risk Factors" in this prospectus beginning on page SA-5, and in the documents incorporated by reference into this prospectus.

Our Company

We are a biopharmaceutical company focused on the development of novel immunotherapy biologic agents for the treatment of autoimmune diseases and cancer. Our two principal product candidates in clinical development are described below.

TSO

TSO, or CNDO-201, is a biologic comprising *Trichuris suis* ova, the microscopic eggs of the porcine whipworm, which we believe could be used for the treatment of a range of autoimmune diseases, such as Crohn's disease, or Crohn's, ulcerative colitis, or UC, multiple sclerosis, or MS, autism, psoriasis, Type 1 diabetes, or T1D, psoriatic arthritis and rheumatoid arthritis. In February 2012, we announced positive results from our Phase 1 clinical trial of TSO in 36 patients with Crohn's. The trial was a sequential dose-escalation, double-blind, placebo-controlled study to examine safety and tolerability. TSO was shown to be safe and well tolerated, with no serious treatment-related adverse events reported. To date, a number of investigator-sponsored clinical trials have been conducted using TSO in patients suffering from Crohn's, UC or MS. These studies also demonstrated that TSO is safe and well tolerated. In April 2012, our development partner, Dr. Falk Pharma GmbH, or Falk, reported that an independent data monitoring committee had found no safety concerns and a positive efficacy trend in an interim analysis (blinded to Falk) of clinical data from the initial 120 patients in Falk's ongoing Phase 2 clinical trial in Europe evaluating TSO in Crohn's patients, known as TRUST-II. Based on the committee's recommendations, Falk has advised us that it is increasing the size of its trial and will conduct a subsequent interim analysis at the time the trial reaches approximately 240 patients, which we expect to occur in the fourth quarter of 2013.

In August 2012, we initiated in the United States a Phase 2 clinical trial of TSO, known as TRUST-I, designed to evaluate the safety and efficacy of TSO. In July 2013, we completed the enrollment of TRUST-I in 250 patients with Crohn's and expect to have initial study results in the fourth quarter of 2013.

We have the exclusive rights to TSO in North America, South America and Japan (the "Coronado Territories") under a sublicense agreement with Ovamed GmbH, or Ovamed, as well as a manufacturing and supply agreement with Ovamed to provide us with our clinical and commercial requirements of TSO. In December 2012, we signed the Second Amendment and Agreement to our sublicense agreement with Ovamed, which provides us the exclusive right to manufacture TSO for the Coronado Territories in exchange for certain consideration to Ovamed. We anticipate that we will continue to purchase our Phase 2 TSO supplies and we may purchase at least a portion of our Phase 3 TSO supplies from Ovamed under the current agreement. Thereafter, we plan to manufacture our remaining Phase 3 clinical supplies from our U.S. facility which we plan to establish in Woburn, MA under a lease acquired from Ovamed as part of the agreement. We plan on continuing the build out and site preparation of the manufacturing facility in 2013, after which the facility will be subject to FDA and other regulatory authorities' inspections.

In March 2012, we entered into a Collaboration Agreement with Ovamed and Falk, Ovamed's sublicensee in Europe for gastroenterology indications, under which we agreed to collaborate in the development of TSO for Crohn's. Under the Collaboration Agreement, Falk granted us exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO in Crohn's, including Falk's ongoing Phase 2 clinical trial, for use in North America, South America and Japan. We granted Falk exclusive rights and licenses to data from our clinical trials of TSO in Crohn's for use in Europe. A steering committee comprised of our representatives and representatives of Falk and Ovamed is overseeing the clinical development program for Crohn's, under which we and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn's in the United States and Europe and will share in certain pre-clinical development costs.

CNDO-109

CNDO-109 is a biologic that activates the immune system's natural killer, or NK, cells to seek and destroy cancer cells. We intend to study CNDO-109 initially in patients that have been diagnosed with acute myeloid leukemia, or AML. Preclinical studies have demonstrated that CNDO-109 activated NK cells directly kill cells that cause hematologic malignancies including myeloid leukemia and multiple myeloma, as well as breast, prostate and ovarian cancers. Eight patients with high-risk AML received CNDO-109 activated NK cells in a recent Phase 1 investigator-sponsored trial. Although the primary endpoint of the Phase 1 clinical trial was safety, based on the data obtained from this Phase 1 study, we believe early efficacy was observed. The clinical investigators observed that the majority of patients experienced a longer complete remission than their previous complete remission. In February 2012, we filed an Investigational New Drug application for a multi-center Phase 1/2 clinical trial in patients with relapsed AML. In November

2012, we initiated this trial. In June 2012, the U.S. Food and Drug Administration, or FDA, granted orphan drug designation to CNDO-109 activated NK cells for the treatment of AML and, in September 2012, the U.S. Patent and Trademark Office granted the first U.S. patent covering CNDO-109. We have exclusive worldwide rights to develop and market CNDO-109 under a license agreement with the University College London Business PLC, or UCLB.

Corporate Information

We were incorporated in June 2006 under the laws of Delaware. Our principal executive offices are located at 24 New England Executive Park, Burlington, MA 01803 and our telephone number is (781) 652-4500. Our website address is www.coronadobiosciences.com. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this prospectus, and you should not consider it part of this prospectus or part of any prospectus supplement.

The Offering	
Common stock offered by us pursuant to this prospectus	Shares of our common stock having an aggregate offering price of up to $70,000,000.
Manner of offering	“At the market” offering that may be made from time to time on The NASDAQ Capital Market or other market for our common stock in the United States through our agent, MLV. See the section entitled “Plan of Distribution” below.
Use of proceeds	We intend to use the net proceeds of this offering for our operations, including, but not limited to, general corporate purposes, which may include research and development expenditures, clinical trial expenditures, manufacture and supply of product and working capital. See the section entitled “Use of Proceeds” below.
Risk factors	See “Risk Factors” beginning on page SA-5 and the other information included in, or incorporated by reference into, this prospectus for a discussion of certain factors you should carefully consider before deciding to invest in shares of our common stock.
NASDAQ Capital Market symbol	CNDO

RISK FACTORS

Investing in our common stock involves risk. Before deciding whether to invest in our common stock, you should consider carefully the risks and uncertainties described below, as updated or superseded by the risks and uncertainties described under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus, together with other information in this prospectus, the information and documents incorporated by reference herein and any free writing prospectus that we may authorize for use in connection with this offering. The risks we describe in these documents are not the only ones we face, but those that we consider to be material. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section below entitled "Forward-Looking Statements."

Risks Related to our Business and Industry

We are a development stage company and have a limited operating history upon which to base an investment decision.

We are a clinical development stage biopharmaceutical company. We have engaged primarily in research and development activities since inception, have not generated any revenues from product sales and have incurred significant net losses since our inception. As of June 30, 2013, we had an accumulated deficit of approximately $103.7 million. We have not demonstrated our ability to perform the functions necessary for the successful commercialization of any of our products. The successful commercialization of any of our products will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of our product candidates. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to commercialize TSO, CNDO-109 or any other future products and the advisability of investing in our securities.

Our product candidates are at an early stage of development and may not be successfully developed or commercialized.

Our two product candidates, TSO and CNDO-109, are in the early stage of development and will require substantial further capital expenditures, development, testing, and regulatory clearances prior to commercialization. The development and regulatory approval process takes several years and it is not likely that either TSO or CNDO-109, even if successfully developed and approved by the FDA, would be commercially available for five or more years. Of the large number of drugs in development, only a small percentage successfully completes the FDA regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our product candidates could result in the failure of our business and a loss of all of your investment in our company.

Because we in-licensed our product candidates from third parties, any dispute with our licensors or non-performance by us or by our licensors may adversely affect our ability to develop and commercialize the applicable product candidates.

All of our product candidates, including related intellectual property rights, were in-licensed from third parties. Under the terms of our license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach by us. Our licenses require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments depends on our ability to generate cash in the future. These agreements generally require us to use diligent and reasonable efforts to develop and commercialize the product candidate. In the case of TSO, Ovamed licenses TSO from a third party, University of Iowa Research Foundation, or UIRF, in exchange for annual and milestone payments, patent cost reimbursement, royalties based on sales and diligence obligations. Our rights to TSO are, therefore, also subject to Ovamed's performance of its obligations to UIRF, any breach of which we may be required to remedy in order to preserve our rights.

If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partner regarding our rights or obligations under the license agreement, including any conflict, dispute or disagreement arising from our failure to satisfy payment obligations under such agreement, our ability to develop and commercialize the affected product candidate may be adversely affected. Similarly, any such dispute or issue of non-performance between Ovamed and UIRF that we are unable to cure could adversely affect our ability to develop and commercialize TSO. Any loss of our rights under our license agreements could delay or completely terminate our product development efforts for the affected product candidate.

Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Pharmaceutical development has inherent risk. We will be required to demonstrate through well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later-stage clinical trials will be successful as product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. We also may need to conduct additional clinical trials that are not currently anticipated. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of a New Drug Application or Biologics License Application ("BLA") to the FDA and even fewer are approved for commercialization.

Any product candidates we advance into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates, TSO and CNDO-109, are subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive approval of a BLA from the FDA. The process of obtaining BLA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Our development of CNDO-109, which is an individualized immunotherapy, may in particular be affected because to date the FDA has only approved one individualized immunotherapy treatment, Provenge by Dendreon Corporation. In addition to the significant clinical testing requirements, our ability to obtain marketing approval for these products depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or another regulatory agency can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may fail to approve our manufacturing processes or facilities or those of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, recent events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product

candidate and generating revenues from its sale. For example, in Phase 1/2 oncology trials, dose limiting toxicity, or DLT, stopping rules are commonly applied. Our CNDO-109 Phase 1/2 trial is subject to a set of DLTs that could suspend or stop dose escalation by predetermined criteria, including allergic reactions, prolonged aplasia or other organ toxicities of a serious nature.

We have not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product or, if such product candidate is approved for marketing, future adverse events could cause us to withdraw such product from the market.

Delays in the commencement of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Investigator Review Board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Suspensions or delays in the completion of clinical testing could result in increased costs to us and delay or prevent our ability to complete development of that product or generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements and on a timely basis. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- stopping rules contained in the protocol;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and the likelihood of a successful completion of a clinical trial. If we experience delays in the completion of, or if we must suspend or terminate, any clinical trial of any product candidate, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, any of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

Even if approved, TSO, CNDO-109 or any other product candidates that we may develop and market may be later withdrawn from the market or subject to promotional limitations.

We may not be able to obtain the labeling claims necessary or desirable for the promotion of our product candidates if approved. We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory or if adverse events or other safety issues arise after approval, the FDA or a comparable regulatory agency in another country may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and/or time consuming to complete. In addition, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our products if approved.

Though we are in the process of establishing a U.S. manufacturing facility, we currently rely completely on Ovamed, and other third parties to manufacture our supplies of TSO. Our dependence on third party suppliers or our inability to successfully produce TSO could adversely impact our business.

While we are establishing a manufacturing facility in Woburn MA for a portion of our Phase 3 clinical supplies and our potential commercial supplies of TSO, we currently rely exclusively on Ovamed to supply us with our requirements of TSO. Ovamed produces TSO at only one facility in Germany, where it also produces product for third parties, including Falk. If Ovamed becomes unable or unwilling to deliver sufficient quantities of TSO to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there would be a significant interruption of our TSO supply, which would materially adversely affect clinical development and potential commercialization of the product. In the event that the FDA or such other agencies determine that we, Ovamed or Ovamed's third-party suppliers have not complied with cGMP, our clinical trials could be terminated or subjected to a clinical hold until such time as we or Ovamed are able to obtain appropriate replacement material. Furthermore, if Ovamed, we or any other contract manufacturer who supply Ovamed or us cannot successfully manufacture material that conforms to our specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for TSO. We, Ovamed and our third-party suppliers are and will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of our or Ovamed's facilities or operations or of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

We do and will also rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture TSO. We will and Ovamed does rely on a single source of ova. We do not have any control over the process or timing of the acquisition of raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

We or Ovamed may not have the resources or capacity to commercially manufacture TSO, if approved, and we will likely continue to be dependent upon third party manufacturers at least until we have completed establishing our manufacturing facility in Woburn, MA and potentially even thereafter. Our current inability or our dependence on third parties to manufacture and supply us with clinical trial materials and any approved products may adversely affect our ability to develop and commercialize TSO on a timely basis or at all.

We currently rely completely on Progenitor Cell Therapy, or PCT, and other third parties to manufacture our preclinical and clinical pharmaceutical supplies of CNDO-109 and expect to continue to rely on these third parties to produce commercial supplies of CNDO-109, and our dependence on third party suppliers could adversely impact our business.

We are completely dependent on third party manufacturers for product supply of CNDO-109. We rely on BioReliance Corporation, or BioReliance, and PCT for our CNDO-109 requirements and our CNDO-109 clinical program would be adversely affected by a significant interruption in the supply of this product. Furthermore, if BioReliance and/or PCT or any other contract manufacturers cannot successfully manufacture material that conforms to our specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for CNDO-109. Our third-party suppliers will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. In the event that the FDA or such other agencies determine that our third-party suppliers have not complied with cGMP, our clinical trials could be terminated or subjected to a clinical hold until such time as we are able to obtain appropriate replacement material. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

We will also rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture CNDO-109. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of CNDO-109 or the raw material components thereof for an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of CNDO-109.

We do not expect to have the resources or capacity to commercially manufacture CNDO-109, if approved, and will likely continue to be dependent upon third party manufacturers. Our dependence on third parties to manufacture and supply us with clinical trial materials and any approved products may adversely affect our ability to develop and commercialize CNDO-109 on a timely basis or at all.

We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We intend and do use CROs to conduct our planned clinical trials and will and do rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. Our CROs, investigators and other third parties will and do play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, fail to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

If our competitors develop treatments for the target indications of our product candidates that are approved more quickly, marketed more successfully or demonstrated to be more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies, as well as new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We also may compete with these organizations to recruit management, scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other biological and pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market, distribute and sell any products we may successfully develop, we may not be able to effectively market and sell any such products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates, and must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or jointly with a partner, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch. If we, or our partners, are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may successfully develop, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third parties on acceptable terms, or at all.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that it generates from their sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- acceptance of the product by the target population;

- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

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

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

Because we have limited financial and managerial resources, we have focused on two research programs and product candidates, TSO and CNDO-109, for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or, particularly with respect to TSO, for other indications for which there may be a greater likelihood of success or may prove to have greater commercial potential. Notwithstanding our investment to date and anticipated future expenditures on TSO and CNDO-109, we have not yet developed, and may never successfully develop, any marketed treatments using these products. Research programs to identify new product candidates or pursue alternative indications for current product candidates require substantial technical, financial and human resources. Although we intend to and do support certain investigator-sponsored clinical trials of TSO evaluating various indications, these activities may initially show promise in identifying potential product candidates or indications, yet fail to yield product candidates or indications for further clinical development.

We may incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and intend to maintain product liability insurance relating to our clinical trials, our coverage may not be sufficient to cover claims that may be made against us and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that may be approved for marketing. Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to our product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability or the ability of our collaborators to commercialize any of our product candidates that we successfully develop may depend, in part, on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our product candidates to enable us or our collaborators to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

If we fail to attract and retain key management and clinical development personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. As a company with a limited number of personnel, we are highly dependent on the development, regulatory, commercial and financial expertise of the members of our senior management, in particular Harlan F. Weisman, M.D., our chairman and chief executive officer. The loss of this individual or the services of any of our other senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical companies, as well as universities and research organizations. If we are not able to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

We use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our success will depend upon intellectual property, proprietary technologies and regulatory market exclusivity periods, and the intellectual property protection for our product candidates depends significantly on third parties.

Our success will depend, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. UIRF, Falk and Ovamed are responsible for prosecuting and maintaining patent protection relating to their respective patents relating to TSO and UCLB is responsible for prosecuting and maintaining patent protection for CNDO-109, in each case at our expense for our territories. If UIRF, Falk, Ovamed and/or UCLB fail to appropriately prosecute and maintain patent protection for these product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of which have substantially greater resources than we or our partners and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing products.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or come upon this same or similar information independently.

We also intend to rely on our ability to obtain and maintain a regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is currently 12 years from the date of marketing approval, there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period, as proposed by President Obama. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect us.

In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the America Invents Act, was signed into law, and includes a number of significant changes to United States patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The U.S. Patent and Trademark Office implemented the America Invents Act on March 16, 2013, and it remains to be seen how the judicial system and the U.S. Patent and Trademark Office will interpret and enforce these new laws. Accordingly, it is not clear what impact, if any, the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we or our partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends on our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign our products or processes to avoid infringement;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. 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.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to us.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims that we or these consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Relating to our Finances, Capital Requirements and Other Financial Matters

We are a development stage company with a history of operating losses that are expected to continue and we are unable to predict the extent of future losses, whether we will generate significant or any revenues or whether we will achieve or sustain profitability.

We are a development stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses in all periods since our inception in June 2006, including losses of approximately $10.0 million, $36.4 million and $27.6 million for the years ended December 31, 2010, 2011 and 2012, respectively, and approximately $19.5 million for the six months ended June 30, 2013. At June 30, 2013, we had an accumulated deficit of approximately $103.7 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant or any revenues or if we will ever achieve or sustain profitability.

Our existing $15.0 million term loan agreement contains affirmative and negative covenants that impose significant restrictions on our business and financing activities. If we default on our obligations, whether due to events beyond our control or otherwise, the lender would have a right to foreclose on substantially all of our assets, other than our intellectual property. A default could materially and adversely affect our operating results and our financial condition. The loan agreement also contains several affirmative and negative covenants that impose significant restrictions on our business and operations. Our failure to comply with the covenants contained in the loan agreement may result in the declaration of an event of default that, if not cured or waived, could cause all amounts outstanding under the loan agreement to become due and payable immediately and could cause the lender to foreclose on the collateral securing the indebtedness, including our cash, cash equivalents and short-term investments. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. In addition, the loan agreement may limit our ability to finance future operations or satisfy capital needs or to engage in, expand or pursue our business activities. It may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2010, 2011 and 2012 we incurred research and development expenses of approximately $8.3 million, $8.6 million and $17.5 million, respectively. Since our inception in 2006 to June 30, 2013, we have incurred research and development expenses of approximately $55.8 million. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates, establishing manufacturing capabilities for TSO in the United States, and purchasing clinical trial materials from our suppliers. We believe that our current cash will be sufficient to meet our anticipated cash requirements at least for the next twelve months and that we will require substantial additional funds to support our continued research and development activities, including costs of preclinical studies and clinical trials, obtaining regulatory approvals and potential commercialization and for the payment of principal and interest under our existing loan agreement. We have based this estimation on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration or licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes Oxley Act of 2002 and related rules, our management is be required to report on, and our independent registered public accounting firm is required to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, or the Exchange Act, we may need to further upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. If material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

Risks Associated with our Capital Stock

The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our common stock;
- delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors, product manufacturers or our ability to produce TSO;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

Almost all of our 33,324,267 outstanding shares of common stock as of August 16, 2013, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, or an effective registration statement. Pursuant to our shelf registration statement on Form S-3/A filed in August 2013, we may sell up to $200,000,000 of our equity securities over the next three years. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock. We sold 3,361 shares of our common stock resulting in net proceeds to us of $19,000 in 2012 and, from January 1, 2013 through to August 16, 2013, we sold 8,470,806 shares of our common stock resulting in net proceeds to us of $73.4 million pursuant to our Form S-3 filed in September 2012.

We have never paid and do not intend to pay cash dividends. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Provisions in our certificate of incorporation, our bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation, as amended and our amended and restated bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our board of directors.

Delaware General Corporation Law generally prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless, upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, or the business combination was approved in a prescribed manner.

The existence of the forgoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Risks Associated with this Offering

We have broad discretion in the use of the net proceeds of this offering and may not use them effectively.

We intend to use the net proceeds from this offering for our operations, including, but not limited to, general corporate purposes, which may include research and development expenditures, clinical trial expenditures, manufacture and supply of product and working capital. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates.

You may experience immediate and substantial dilution in the book value per share of the common stock you purchase.

Because the prices per share at which shares of our common stock are sold in this offering may be substantially higher than the book value per share of our common stock, you may suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. The shares sold in this offering, if any, will be sold from time to time at various prices. After giving effect to the sale of our common stock in the maximum aggregate offering amount of $70,000,000 at an assumed offering price of $7.73 per share, the last reported sale price of our common stock on The NASDAQ Capital Market on August 16, 2013, and after deducting estimated offering commissions payable by us, our net tangible book value as of June 30, 2013 would have been $117,141,000, or $3.03 per share of common stock. This represents an immediate increase in the net tangible book value of $1.39 per share to our existing stockholders and an immediate and substantial dilution in net tangible book value of $4.70 per share to new investors who purchase our common stock in the offering. See “Dilution” for a more detailed discussion of the dilution you may incur in connection with this offering.

FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. Any forward-looking statements are based on our current expectations and projections about future events and are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

Some of the information in this prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of the federal securities laws. These statements include, among others, statements about:

- our plans to develop TSO and CNDO-109;
- ongoing and planned clinical trials of TSO and CNDO-109, particularly the timing for initiation, enrollment and outcome;
- the expected timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the potential indications for our product candidates;
- our intellectual property position;
- our manufacturing capabilities and strategy;
- our plans relating to manufacturing, supply and other collaborative agreements; and
- our estimates regarding expenses, capital requirements and needs for additional financing.

You should read this prospectus and the documents that we reference herein completely and with the understanding that our actual future results may be materially different from what we concurrently expect. You should assume that the information appearing in this prospectus and any document incorporated by reference is accurate as of its date only. Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus and any document incorporated herein by reference, and particularly our forward-looking statements, by these cautionary statements.

USE OF PROCEEDS

The amount of proceeds from this offering will depend upon the number of shares of our common stock sold and the market price at which they are sold. There can be no assurance that we will be able to sell any shares under or fully utilize the sales agreement with MLV as a source of financing.

We intend to use the net proceeds of this offering for our operations, including, but not limited to, general corporate purposes, which may include research and development expenditures, clinical trial expenditures, manufacture and supply of product and working capital. The precise amount, use and timing of the application of such proceeds will depend upon our funding requirements and the availability and cost of other capital. Pending application of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term, investment-grade, interest-bearing securities and/or savings accounts.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value of our common stock as of June 30, 2013 was approximately $48,558,000, or approximately $1.64 per share of common stock based upon 29,605,524 shares outstanding at that time. Net tangible book value per share is equal to our total tangible assets, less our total liabilities, divided by the total number of shares outstanding as of June 30, 2013.

After giving effect to the sale of our common stock in the aggregate amount of $70,000,000 at an assumed offering price of $7.73 per share, the last reported sale price of our common stock on The NASDAQ Capital Market on August 16, 2013, and after deducting estimated offering commissions payable by us, our net tangible book value as of June 30, 2013 would have been $117,141,000, or $3.03 per share of common stock based on 38,661,151 shares of common stock outstanding on a pro forma basis at that time. This represents an immediate increase in net tangible book value of $1.39 per share to our existing stockholders and an immediate dilution in net tangible book value of $4.70 per share to new investors in this offering.

The following table illustrates this calculation on a per share basis as of June 30, 2013:

Offering price per share	$7.73
Net tangible book value per share	$1.64
Increase in net tangible book value per share attributable to the offering	$1.39
Pro forma net tangible book value per share after giving effect to the offering	$3.03
Dilution in net tangible book value per share to new investors	$4.70

The foregoing table does not give effect to the exercise of any outstanding options or warrants. To the extent options and warrants are exercised, there may be further dilution to new investors.

The number of shares of our common stock to be outstanding immediately after this offering on a pro forma basis is based on 29,605,524 shares of our common stock outstanding as of June 30, 2013 and excludes:

- 1,047,457 shares issuable upon exercise of outstanding warrants as of August 16, 2013 with a weighted average exercise price of $6.31;
- 4,180,503 shares issuable upon exercise of outstanding options as of August 16, 2013 with a weighted average exercise price of $4.84; and
- 3,606,049 shares sold between July 1 and August 16, 2013 pursuant to our prior at the market offerings.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock and we are currently prohibited from making any dividend payment under the terms of our loan and security agreement with Hercules Technology Growth Capital, Inc. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future.

PLAN OF DISTRIBUTION

We have entered into an At Market Issuance Sales Agreement, as amended, with MLV to issue and sell up to $70,000,000 worth of our common stock from time to time under this prospectus. MLV will act as agent in the offering, subject to certain limitations, including the number of shares registered under the registration statement to which the offering relates. The At Market Issuance Sales Agreement, as amended, is referred to herein as the sales agreement.

The sales, if any, of shares made under the sales agreement will be made by any method that is deemed an "at the market" offering as defined in Rule 415 promulgated under the Securities Act, including by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by MLV and us. We may instruct MLV not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or MLV may suspend the offering of common stock upon notice and subject to other conditions. As an agent, MLV will not engage in any transactions that stabilize the price of our common stock.

Each time we wish to issue and sell common stock under the sales agreement, we will notify MLV of the number of shares to be issued, the dates on which such sales are anticipated to be made, any minimum price below which sales may not be made and other sales parameters as we deem appropriate. Once we have so instructed MLV, unless MLV declines to accept the terms of the notice, MLV has agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such shares up to the amount specified on such terms. The obligations of MLV under the sales agreement to sell our common stock is subject to a number of conditions that we must meet.

We will pay MLV commissions for its services in acting as agent in the sale of common stock. MLV will be entitled to a commission of up to 3% of the gross proceeds from the sale of common stock offered hereby. In addition, we have agreed to reimburse certain expenses of MLV in an amount not to exceed $25,000. We estimate that the total expenses for the offering, excluding compensation payable to MLV under the terms of the sales agreement, will be approximately $0.2 million.

Settlement for sales of common stock will occur on the third business day following the date on which any sales are made, or on some other date that is agreed upon by us and MLV in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sale of the common stock on our behalf, MLV may, and will with respect to sales effected in an "at the market" offering, be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of MLV may be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act. We have also agreed to reimburse MLV for certain other specified expenses.

The offering will terminate as permitted under the sales agreement.

MLV and its affiliates may in the future provide various investment banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, MLV will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

LEGAL MATTERS

The validity of the shares of our common stock offered hereby has been passed upon for us by Wyrick Robbins Yates & Ponton LLP, Raleigh, NC. LeClairRyan, A Professional Corporation, New York, NY, is counsel for MLV in connection with this offering.

EXPERTS

The consolidated financial statements and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Annual Report on Internal Control over Financial Reporting) incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2012 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION ABOUT US

We are subject to the reporting requirements of the Exchange Act, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC's web site at http://www.sec.gov.

This prospectus is only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act, and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The following documents filed by us with the SEC are incorporated by reference in this prospectus:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the SEC on March 18, 2013;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, filed with the SEC on May 9, 2013 and our Quarterly Reports on Form 10-Q and 10-Q/A for the quarter ended June 30, 2013, filed with the SEC on August 5 and August 12, 2013, respectively;
- our Current Reports on Form 8-K filed with SEC on January 3, 7 and 9, February 25, April 11, 24 and 29, June 4 and 21, July 1 and 29, and August 5, 2013 (only Items 1.01, 5.02 and Exhibit 10.51 filed therein); and
- the description of our capital stock contained in our registration statement on Form S-1 filed with the SEC on September 28, 2011, including any amendment or report for the purpose of updating such description.

In addition, all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed in such forms that are related to such items unless such Form 8-K expressly provides to the contrary) subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, before the date our offering is terminated or completed are deemed to be incorporated by reference into, and to be a part of, this prospectus.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents in writing to Coronado Biosciences, Inc. Attention: Dale Ritter, Senior Vice President, Finance, 24 New England Executive Park, Burlington, MA 01803, or by phone at (781) 652-4500

You should rely only on information contained in, or incorporated by reference into, this prospectus and any prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference in this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

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$70,000,000

Common Stock

PROSPECTUS

The date of this prospectus is August 20, 2013