

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

CORONADO BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary standard industrial
classification code number)

20-5157386
(I.R.S. employer
identification number)

**15 New England Executive Park
Burlington, MA 01803
(781) 238-6621**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Bobby W. Sandage, Jr., Ph.D., Chief Executive Officer
15 New England Executive Park
Burlington, MA 01803
(781) 238-6621

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Fran Stoller, Esq.
David J. Levine, Esq.
Loeb & Loeb LLP
345 Park Avenue
New York, New York 10154
(212) 407-4000
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b2 of the Exchange Act.

Large Accelerated Filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of each Class of Security being Registered	Amount being Registered (1)	Proposed Maximum Offering Price Per Security	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, \$0.001 par value per share (2)	(3)(4)	(3)	(3)	(3)
Preferred Stock, \$0.001 par value per share (2)	(3)(4)	(3)	(3)	(3)
Warrants (2)	(3)(4)	(3)	(3)	(3)
Units	(3)(4)	(3)	(3)	(3)
Total Offering	\$75,000,000	100%	\$75,000,000(2)	\$8,595(5)

- (1) This registration statement includes \$75,000,000 of securities which may be issued by the registrant from time to time in indeterminate amounts and at indeterminate times. Securities registered hereunder may be sold separately, together or as units with other securities registered hereunder.
- (2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended, or the Securities Act.
- (3) Not required to be included in accordance with General Instruction II.D. of Form S-3 under the Securities Act.
- (4) Subject to footnote (1), there is also being registered hereunder such indeterminate amount of securities (including shares or other classes of the registrant’s stock that may be issued upon reclassification of unissued, authorized stock of the registrant) as may be issued in exchange for or upon conversion of, as the case may be, the other securities registered hereunder. No separate consideration will be received for any securities registered hereunder that are issued in exchange for, or upon conversion of, as the case may be, such other securities.
- (5) Paid herewith.

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

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

SUBJECT TO COMPLETION, SEPTEMBER 17, 2012

PRELIMINARY PROSPECTUS



\$75,000,000

**Common Stock
Preferred Stock
Warrants
Units**

We may offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, warrants, or units having a maximum aggregate offering price of \$75,000,000. When we decide to sell a particular class or series of securities, we will provide specific terms of the offered securities in a prospectus supplement.

The prospectus supplement may also add, update or change information contained in or incorporated by reference into this prospectus. However, no prospectus supplement shall offer a security that is not registered and described in this prospectus at the time of its effectiveness. You should read this prospectus and any prospectus supplement, as well as the documents incorporated by reference or deemed to be incorporated by reference into this prospectus, carefully before you invest.

This prospectus may not be used to offer or sell our securities unless accompanied by a prospectus supplement relating to the offered securities.

Our common stock is traded on The NASDAQ Capital Market under the symbol "CNDQ." Each prospectus supplement will contain information, where applicable, as to our listing on The NASDAQ Capital Market or any other securities exchange of the securities covered by the prospectus supplement.

These securities may be sold directly by us, through dealers or agents designated from time to time, to or through underwriters or through a combination of these methods. See "Plan of Distribution" in this prospectus. We may also describe the plan of distribution for any particular offering of our securities in a prospectus supplement. If any agents, underwriters or dealers are involved in the sale of any securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in a prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in a prospectus supplement.

Investing in our securities involves various risks. See "[Risk Factors](#)" on page 4 for more information on these risks. Additional risks, if any, will be described in the prospectus supplement related to a potential offering under the heading "Risk Factors." You should review that section of the related prospectus supplement for a discussion of matters that investors in such securities should consider.

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 or any accompanying prospectus supplement. Any representation to the contrary is a criminal offense.

The date of this Prospectus is _____, 2012

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. Under this shelf registration process, we may offer from time to time securities having a maximum aggregate offering price of \$75,000,000. Each time we offer securities, we will prepare and file with the SEC a prospectus supplement that describes the specific amounts, prices and terms of the securities we offer. The prospectus supplement also may add, update or change information contained in this prospectus or the documents incorporated herein by reference. You should read carefully both this prospectus and any prospectus supplement together with additional information described below under the caption “Where You Can Find More Information.”

This prospectus does not contain all the information provided in the registration statement we filed with the SEC. For further information about us or our securities offered hereby, you should refer to that registration statement, which you can obtain from the SEC as described below under “Where You Can Find More Information.”

You should rely only on the information contained or incorporated by reference in this prospectus or a prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities, in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the SEC and incorporated by reference, is accurate as of the date of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates.

We may sell securities through underwriters or dealers, through agents, directly to purchasers or through a combination of these methods. We and our agents reserve the sole right to accept or reject in whole or in part any proposed purchase of securities. The prospectus supplement, which we will prepare and file with the SEC each time we offer securities, will set forth the names of any underwriters, agents or others involved in the sale of securities, and any applicable fee, commission or discount arrangements with them. See “Plan of Distribution.”

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

The following summary, because it is a summary, may not contain all the information that may be important to you. This prospectus incorporates important business and financial information about the Company that is not included in, or delivered with this prospectus. Before making an investment, you should read the entire prospectus carefully. You should also carefully read the risks of investing discussed under “Risk Factors” and the financial statements included in our other filings with the SEC, including in our Annual Report on Form 10-K, as amended, which we initially filed with the SEC on March 29, 2012. This information is incorporated by reference into this prospectus, and you can obtain it from the SEC as described below under the headings “Where You Can Find Additional Information About Us” and “Incorporation of Certain Documents by Reference.”

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in the prospectus but not delivered with the prospectus. You may request a copy of these filings, excluding the exhibits to such filings which we have not specifically incorporated by reference in such filings, at no cost, by writing us at the following address: Coronado Biosciences, Inc., 15 New England Executive Park, Burlington, MA 01803. Our telephone number is (781) 238-6621.

The Offering

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the “SEC”) utilizing a shelf registration process. Under this shelf registration process, we may sell any combination of:

- common stock;
- preferred stock;
- warrants to purchase any of the securities listed above; and/or
- units consisting of one or more of the foregoing,

in one or more offerings up to a total dollar amount of \$75,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that specific offering and include a discussion of any risk factors or other special considerations that apply to those securities. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with the additional information described under the heading “Where You Can Find Additional Information About Us.”

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, for the treatment of autoimmune diseases, such as Crohn’s disease, or Crohn’s, ulcerative colitis, or UC, and multiple sclerosis, or MS. 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 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. 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 250 patients, which we expect to occur in mid-2013. In August 2012, we initiated a Phase 2 clinical trial of TSO, known as TRUST-1, designed to evaluate the safety and efficacy of TSO in approximately 220 patients with Crohn’s and expect to have initial study results in the second half of 2013. We have the exclusive rights to TSO in North America, South America and Japan 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 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, or IND, for a multi-center Phase 1/2 clinical trial in patients with relapsed AML that we currently plan to initiate in the second half of 2012. In June 2012, the FDA granted orphan drug designation to CNDO-109 activated NK cells for the treatment of AML. We have exclusive worldwide rights to develop and market CNDO-109 under a license agreement with the University College London Business PLC, or UCLB.

Our principal executive offices are located 15 New England Executive Park, Burlington, MA 01803. Our telephone number is (781) 238-6621.

RISK FACTORS

Investing in our securities involves risk. The prospectus supplement applicable to a particular offering of securities will contain a discussion of the risks applicable to an investment in us and to the particular types of securities that we are offering under that prospectus supplement. Before making an investment decision, you should carefully consider the following risk factors as well as the risks described under “Risk Factors” in the applicable prospectus supplement and the risks described in our most recent Annual Report on Form 10-K, or any updates to our risk factors in our Quarterly Reports on Form 10-Q, together with all of the other information appearing in or incorporated by reference into this prospectus and any applicable prospectus supplement, in light of your particular investment objectives and financial circumstances. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment.

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, 2012, we had an accumulated deficit of approximately \$69.6 million. We have not demonstrated our ability to perform the functions necessary for the successful commercialization of any 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 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 NDA, or Biologics License Application, or 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. 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 and other 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 the manufacturing processes or facilities 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 planned 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;

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- 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 site 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, many 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.

We rely completely on OvaMed, Progenitor Cell Therapy, or PCT, and other third parties to manufacture our preclinical and clinical pharmaceutical supplies and expect to continue to rely on OvaMed and other third parties to produce commercial supplies of any approved product candidate, and our dependence on third party suppliers could adversely impact our business.

We are completely dependent on third party manufacturers for product supply. In particular, we rely exclusively on OvaMed to supply us with our requirements of TSO. OvaMed is the sole supplier of this product, which it is currently producing at only one facility in Germany, where it also is producing product for clinical trials by 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. Similarly, 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 OvaMed, 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 our product candidates. 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 our product candidates and, in the case of TSO, OvaMed relies on a single source of ova. 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 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 do not expect to have the resources or capacity to commercially manufacture any of our proposed products, 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 our products 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 to use CROs to conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties 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, if 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;

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- 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 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 Glenn L. Cooper, M.D., our executive chairman, and Bobby W. Sandage, Jr., Ph.D., our president and chief executive officer. The loss of such individuals 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 United States 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 United States 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, reductions to this period have been proposed. 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, United States 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 Leahy-Smith 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 United States Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith 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 upon 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 United States 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 revenues or whether we will achieve or sustain profitability.

We are a company in the development stage 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 \$3.7 million, \$10.0 million, and \$36.4 million for the years ended December 31, 2009, 2010 and 2011, respectively, and \$13.0 million in the six months ended June 30, 2012. At June 30, 2012, we had an accumulated deficit of

approximately \$69.6 million. We expect to make substantial expenditures and incur increasing operating costs 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 revenues or if we will ever achieve or sustain profitability.

Our existing 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. A default could materially and adversely affect our operating results and our financial condition.

Our existing \$15.0 million term loan agreement contains several affirmative and negative covenants that impose significant restrictions on our business and operations. In addition, the loan is secured by substantially all of our assets, other than our intellectual property. 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 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, 2009, 2010 and 2011, we incurred research and development expenses of approximately \$2.3 million, \$8.3 million and \$8.6 million, respectively, and \$9.1 million in the six months ended June 30, 2012. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We believe that our current cash will be sufficient to meet our anticipated cash requirements into the first quarter of 2014 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 estimate, however, 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 currently have no agreements to obtain any additional financing and 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.

We received a report from our independent registered public accounting firm with an explanatory paragraph for the year ended December 31, 2011 with respect to our ability to continue as a going concern. The existence of such a report may adversely affect our stock price and our ability to raise capital. There is no assurance that we will not receive a similar report for our year ending December 31, 2012.

In their report dated March 29, 2012, our independent registered public accounting firm expressed substantial doubt about our ability to continue as a going concern. We have incurred losses and negative cash flows from operations since inception, have an accumulated deficit as of December 31, 2011 and June 30, 2012 and require additional financing to fund future operations. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities.

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, or SOX, for the year ending December 31, 2012, our management will be required to report on, and our independent registered public accounting firm will be 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.

Prior to 2011, we did not have sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary for, or adequate documented accounting policies and procedures to support effective, internal controls. These material weaknesses contributed to audit adjustments for the years ended December 31, 2010, 2009 and 2008. While we have commenced the process of documenting, reviewing and improving our internal controls over financial reporting for compliance with Section 404 of SOX and have made efforts to improve our internal controls and accounting policies and procedures, including hiring new accounting personnel and engaging external temporary resources, we may in the future identify deficiencies and weaknesses in our internal controls. 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

One of our directors and principal stockholders can individually control our direction and policies, and his interests may be adverse to the interests of our other stockholders.

At June 30, 2012, Lindsay A. Rosenwald, M.D., a member of our board of directors, beneficially owned approximately 14.7% of our issued and outstanding capital stock, and certain trusts established for the benefit of Dr. Rosenwald and his family members additionally beneficially owned an aggregate of approximately 6.0% of our issued and outstanding capital stock. By virtue of his holdings and his membership on our board of directors, Dr. Rosenwald may influence the election of the members of our board of directors, our management and our affairs and may make it difficult for us to consummate corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders. In addition, Dr. Rosenwald is an affiliate of National Securities Corporation, or National, which acted as an underwriter of our June 2012 public offering of common stock. National received related commissions of \$187,000 in connection with the offering. Dr. Rosenwald purchased at the public offering price 200,000 shares of common stock in the offering.

In connection with our Series C Financing, National received commissions of \$2.6 million and five-year warrants to purchase an aggregate of 461,263 Series C shares at an exercise price of \$5.59, which were subsequently transferred by National to other individuals and entities and are now exercisable to purchase 458,276 shares of common 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 or product manufacturers;
- 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 24.4 million outstanding shares of common stock, 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. 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 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 by-laws 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 certificate of incorporation, our by-laws 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.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is 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.

FORWARD-LOOKING STATEMENTS

This prospectus or any accompanying prospectus supplement, including the documents that we incorporate by reference, may contain forward-looking statements within the meaning of Section 27A of 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 incorporated by reference herein, 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 any accompanying prospectus supplement and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, 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, any accompanying prospectus supplement and any document incorporated herein 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, any accompanying prospectus supplement and any document incorporated herein by reference, and particularly our forward-looking statements, by these cautionary statements.

USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities covered by this prospectus for general corporate purposes 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. Additional information on the use of net proceeds from an offering of securities covered by this prospectus may be set forth in the prospectus supplement relating to the specific offering.

DESCRIPTIONS OF THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with any applicable prospectus supplement, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to a particular offering the specific terms of the securities offered by that prospectus supplement. We will indicate in the applicable prospectus supplement if the terms of the securities differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, material United States federal income tax considerations relating to the securities.

We may sell from time to time, in one or more offerings:

- shares of our common stock;
- shares of our preferred stock;
- warrants to purchase any of the securities listed above; and/or
- units consisting of one or more of the foregoing.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

Capital Stock

General

The following description of common stock and preferred stock, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus but is not complete. For the complete terms of our common stock and preferred stock, please refer to our certificate of incorporation, as may be amended from time to time, any certificates of designation for our preferred stock, and our bylaws, as amended from time to time. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the specific terms of any series of these securities in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any common stock or preferred stock we offer under that prospectus supplement may differ from the terms we describe below.

As of September 14, 2012, our authorized capital stock consists of 65,000,000 shares, consisting of 50,000,000 shares of common stock par value \$0.001 per share, and 15,000,000 shares of preferred stock, par value \$0.001 per share. The authorized and unissued shares of common stock and the authorized and undesignated shares of preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors will not seek stockholder approval for the issuance and sale of our common stock or preferred stock.

Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 50,000,000 shares of common stock, par value \$0.001 per share. As of September 14, 2012, there were 24,375,749 shares of common stock

outstanding, as well as 3,542,891 shares of common stock subject to outstanding options and warrants. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future. All of our outstanding shares of common stock are fully paid and nonassessable.

Preferred Stock

We are authorized to issue 15,000,000 shares of preferred stock, par value \$0.001 per share. In November 2011, all of our then outstanding shares of preferred stock were converted, on a one-for-one basis, into 11,496,186 shares of our common stock. As of September 14, 2012, there were no shares of preferred stock outstanding and 458,276 shares of preferred stock that are issuable upon the exercise of outstanding warrants that will automatically convert into shares of common stock upon the exercise of such warrants.

Our board of directors may also divide the shares of preferred stock into series and fix and determine the relative rights and preferences of the preferred stock, such as the designation of series and the number of shares constituting such series, dividend rights, redemption and sinking fund provisions, liquidation and dissolution preferences, conversion or exchange rights and voting rights, if any. Issuance of preferred stock by our board of directors will result in such shares having dividend and/or liquidation preferences senior to the rights of the holders of our common stock and could dilute the voting rights of the holders of our common stock. Once designated by our board of directors, each series of preferred stock will have specific financial and other terms that will be described in a prospectus supplement. The description of the preferred stock that is set forth in any prospectus supplement is not complete without reference to the documents that govern the preferred stock. These include our certificate of incorporation, as amended, and any certificates of designation that our board of directors may adopt. Prior to the issuance of shares of each series of preferred stock, the board of directors is required by the Delaware General Corporation Law and our certificate of incorporation to adopt resolutions and file a certificate of designations with the Secretary of State of the State of Delaware. The certificate of designations fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions, including, but not limited to, some or all of the following:

- the number of shares constituting that series and the distinctive designation of that series, which number may be increased or decreased (but not below the number of shares then outstanding) from time to time by action of the board of directors;
- the dividend rate and the manner and frequency of payment of dividends on the shares of that series, whether dividends will be cumulative, and, if so, from which date;
- whether that series will have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights;
- whether that series will have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the board of directors may determine;
- whether or not the shares of that series will be redeemable, and, if so, the terms and conditions of such redemption;
- whether that series will have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund;

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- whether or not the shares of the series will have priority over or be on a parity with or be junior to the shares of any other series or class in any respect;
 - the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights or priority, if any, of payment of shares of that series; and
 - any other relative rights, preferences and limitations of that series.

All shares of preferred stock offered hereby will, when issued, be fully paid and nonassessable, including shares of preferred stock issued upon the exercise of preferred stock warrants or subscription rights, if any.

Although our board of directors has no intention at the present time of doing so, it could authorize the issuance of a series of preferred stock that could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt.

Options/Warrants

As of September 14, 2012, we had outstanding warrants to purchase a total of 1,158,821 shares of our common stock and we had outstanding options to purchase a total of 2,384,070 shares of our common stock.

Warrants

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and any related warrant agreement and warrant certificate. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the specific terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement which includes this prospectus.

General

We may issue warrants for the purchase of common stock and/or preferred stock in one or more series. We may issue warrants independently or together with common stock and/or preferred stock, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we may issue under a separate agreement. We may enter into a warrant agreement with a warrant agent. Each warrant agent may be a bank that we select which has its principal office in the United States. We may also choose to act as our own warrant agent. We will indicate the name and address of any such warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

- the offering price and aggregate number of warrants offered;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase common stock or preferred stock, the number or amount of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which and currency in which these shares may be purchased upon such exercise;

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- the manner of exercise of the warrants, including any cashless exercise rights;
 - the warrant agreement under which the warrants will be issued;
 - the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
 - anti-dilution provisions of the warrants, if any;
 - the terms of any rights to redeem or call the warrants;
 - any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
 - the dates on which the right to exercise the warrants will commence and expire or, if the warrants are not continuously exercisable during that period, the specific date or dates on which the warrants will be exercisable;
 - the manner in which the warrant agreement and warrants may be modified;
 - the identities of the warrant agent and any calculation or other agent for the warrants;
 - federal income tax consequences of holding or exercising the warrants;
 - the terms of the securities issuable upon exercise of the warrants;
 - any securities exchange or quotation system on which the warrants or any securities deliverable upon exercise of the warrants may be listed or quoted; and
 - any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including, in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 P.M. eastern time, the close of business, on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required exercise price by the methods provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate, and in the applicable prospectus supplement, the information that the holder of the warrant will be required to deliver to the warrant agent.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants.

Enforceability of Rights By Holders of Warrants

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act

as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action the holder's right to exercise, and receive the securities purchasable upon exercise of, its warrants in accordance with their terms.

Warrant Agreement Will Not Be Qualified Under Trust Indenture Act

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

Governing Law

Each warrant agreement and any warrants issued under the warrant agreements will be governed by New York law.

Units

We may issue units comprised of one or more of the other securities described in this prospectus or in any prospectus supplement in any combination. Each unit will be issued so that the holder of the unit is also the holder, with the rights and obligations of a holder, of each security included in the unit. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date or upon the occurrence of a specified event or occurrence.

The applicable prospectus supplement will describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any unit agreement under which the units will be issued;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- whether the units will be issued in fully registered or global form.

PLAN OF DISTRIBUTION

We may sell the securities being offered pursuant to this prospectus to or through underwriters, through dealers, through agents, or directly to one or more purchasers or through a combination of these methods. The applicable prospectus supplement will describe the terms of the offering of the securities, including:

- the name or names of any underwriters, if any, and if required, any dealers or agents;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters' compensation;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed or traded.

We may distribute the securities from time to time in one or more transactions at:

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale, directly by us or through a designated agent;
- prices related to such prevailing market prices; or
- negotiated prices.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent, and the underwriters will be obligated to purchase all of the offered securities, if any are purchased.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price, with additional underwriting commissions or discounts, as may be set forth in a related prospectus supplement. The terms of any over-allotment option will be set forth in the prospectus supplement for those securities.

If we use a dealer in the sale of the securities being offered pursuant to this prospectus or any prospectus supplement, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, any agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

In connection with the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the securities for whom they act as agents, in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities, and any institutional investors or others that purchase securities directly for the purpose of resale or distribution, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the common stock by them may be deemed to be underwriting discounts and commissions under the Securities Act.

We may provide agents, underwriters and other purchasers with indemnification against particular civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents, underwriters or other purchasers may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

To facilitate the public offering of a series of securities, persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the market price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than have been sold to them by us. In exercising the over-allotment option granted to those persons. In addition, those persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to underwriters or dealers participating in any such offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

Unless otherwise specified in the applicable prospectus supplement, any common stock sold pursuant to a prospectus supplement will be eligible for listing on The NASDAQ Global Market, subject to official notice of issuance. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

In order to comply with the securities laws of some states, if applicable, the securities offered pursuant to this prospectus will be sold in those states only through registered or licensed brokers or dealers. In addition, in some states securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with.

LEGAL MATTERS

The validity of the shares of our common stock offered hereby has been passed upon for us by Loeb & Loeb LLP, New York, New York.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2011 have been so incorporated in reliance on the report (which contains an explanatory

paragraph relating to the Company's ability to continue as a going concern as described in Note 1 of the financial statements) 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 have filed a registration statement on Form S-3 with the SEC for the securities we are offering by this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information. We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in the prospectus but not delivered with the prospectus. We will provide this information upon oral or written request, free of charge. Any requests for this information should be made by calling or sending a letter to the Secretary of the Company, c/o Coronado Biosciences, Inc., at our office located at 15 New England Executive Park, Burlington, MA 01803. Our telephone number is (781) 238-6621.

We are required to file annual and quarterly reports, current reports, proxy statements, and other information with the SEC. We make these documents publicly available, free of charge, on our website at www.coronadobiosciences.com as soon as reasonably practicable after filing such documents with the SEC. You can read our SEC filings, including the registration statement, on the SEC's website at www.sec.gov. You also may read and copy any document we file with the SEC at its public reference facility at:

Public Reference Room
100 F Street N.E.
Washington, DC 20549.

Please call the SEC at 1-800-732-0330 for further information on the operation of the public reference facilities.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

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

- Annual Report on Form 10-K for the fiscal year ended December 31, 2011, filed on March 29, 2012, and the Annual Report on Form 10-K/A (Amendment No. 1) for the fiscal year ended December 31, 2011, filed on April 26, 2012;
- Quarterly Reports on Form 10-Q for the quarter ended March 31, 2012, filed on May 15, 2012, and the quarter ended June 30, 2012, filed on August 8, 2012;
- Current Reports on Form 8-K filed on February 23, 2012, March 23, 2012, April 25, 2012, April 25, 2012, May 25, 2012, June 26, 2012 and August 28, 2012;
- Definitive Proxy Statement on Schedule 14A filed on July 13, 2012; and
- The description of our common stock set forth in our Form 8-A, filed on December 7, 2011, including any amendment on reports filed for the purpose of updating such description.

We also incorporate by reference all documents we file under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (a) after the initial filing date of the registration statement of which this prospectus is a part and before the effectiveness of the registration statement and (b) after the effectiveness of the registration statement and before the filing of a post-effective amendment that indicates that the securities offered by this prospectus have been sold or that deregisters the securities covered by this prospectus then remaining unsold. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes hereof or of the related prospectus supplement to the extent that a statement in any other subsequently filed document which is also incorporated or deemed to be incorporated herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.



\$75,000,000

**Common Stock
Preferred Stock
Warrants
Units**

PROSPECTUS

, 2012

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in or incorporated by reference into this prospectus. You must not rely on any unauthorized information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not offer to sell any shares in any jurisdiction where it is unlawful. Neither the delivery of this prospectus, nor any sale made hereunder, shall create any implication that the information in this prospectus is correct after the date hereof.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth an estimate of the fees and expenses relating to the issuance and distribution of the securities being registered hereby, other than underwriting discounts and commissions, all of which shall be borne by us. All of such fees and expenses, except for the SEC registration fee, are estimated:

SEC registration fee	\$ 8,595
Transfer agent's fees and expenses	2,500*
Printing and engraving expenses	2,500*
Accounting fees and expenses	10,000*
Legal fees and expenses	25,000*
Miscellaneous	<u>2,500*</u>
Total	<u>\$51,095*</u>

* Estimated

Item 15. Indemnification of Officers and Directors.

Amended and Restated Bylaws

Pursuant to our amended and restated bylaws, our directors and officers will be indemnified to the fullest extent allowed under the laws of the State of Delaware for their actions in their capacity as our directors and officers.

We must indemnify any person made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative ("Proceeding") by reason of the fact that he is or was a director, against judgments, penalties, fines, settlements and reasonable expenses (including attorney's fees) ("Expenses") actually and reasonably incurred by him in connection with such Proceeding if: (a) he conducted himself in good faith, and: (i) in the case of conduct in his own official capacity with us, he reasonably believed his conduct to be in our best interests, or (ii) in all other cases, he reasonably believes his conduct to be at least not opposed to our best interests; and (b) in the case of any criminal Proceeding, he had no reasonable cause to believe his conduct was unlawful.

We must indemnify any person made a party to any Proceeding by or in the right of us, by reason of the fact that he is or was a director, against reasonable expenses actually incurred by him in connection with such proceeding if he conducted himself in good faith, and: (a) in the case of conduct in his official capacity with us, he reasonably believed his conduct to be in our best interests; or (b) in all other cases, he reasonably believed his conduct to be at least not opposed to our best interests; provided that no such indemnification may be made in respect of any proceeding in which such person shall have been adjudged to be liable to us.

No indemnification will be made by unless authorized in the specific case after a determination that indemnification of the director is permissible in the circumstances because he has met the applicable standard of conduct.

Reasonable expenses incurred by a director who is party to a proceeding may be paid or reimbursed by us in advance of the final disposition of such Proceeding in certain cases.

We have the power to purchase and maintain insurance on behalf of any person who is or was our director, officer, employee, or agent or is or was serving at our request as an officer, employee or agent of another corporation, partnership, joint venture, trust, other enterprise, or employee benefit plan against any liability asserted against him and incurred by him in any such capacity or arising out of his status as such, whether or not we would have the power to indemnify him against such liability under the provisions of the amended and restated bylaws.

Delaware Law

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. Our amended and restated certificate of incorporation and amended and restated bylaws provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

Indemnification Agreements

As permitted by the Delaware General Corporation Law, we have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, that require us to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, damages, judgments, fines,

settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of us or any of our affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Item 16. Exhibits.

<u>Exhibit Number</u>	<u>Description of Document</u>
1.1*	Form of underwriting agreement with respect to common stock, preferred stock or warrants.
4.1*	Form of specimen stock certificate, if any.
4.2*	Form of underwriter warrant, if any.
4.3*	Form of specimen certificate for preferred stock of registrant, if any.
4.4*	Certificate of designation for preferred stock, if any.
4.5*	Form of warrant agreement and warrant certificate, if any.
4.6*	Form of unit agreement and unit certificate, if any.
5.1**	Opinion of Loeb & Loeb LLP, as to legality of certain securities being registered.
23.1**	Consent of PricewaterhouseCoopers LLP.
24.1**	Power of Attorney (included on signature pages to the registration statement).

* To the extent applicable, to be filed by a post-effective amendment or as an exhibit to a document filed under the Securities Exchange Act, as amended, and incorporated by reference herein.

** Filed herewith.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement. Provided, however, that the undertakings set forth in paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) above do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act that are incorporated by reference in the registration statements or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of the registration statement

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, as amended, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(1) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(2) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(d) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of

the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(e) The undersigned registrant hereby undertakes that: (i) for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall of 1933 be deemed to be part of the registration statement as of the time it was declared effective; and (ii) for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(f) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets the requirements for filing on Form S-3 and has duly caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Burlington, State of Massachusetts, on the 17th day of September, 2012.

CORONADO BIOSCIENCES, INC.

By: /s/ Bobby W. Sandage, Jr.

Name: Bobby W. Sandage, Jr., Ph.D.

Title: Chief Executive Officer

POWER OF ATTORNEY

KNOWN ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Bobby W. Sandage and Dale Ritter as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this registration statement, and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
<u>/s/ Glenn L. Cooper</u> Glenn L. Cooper, M.D.	Executive Chairman of the Board of Directors	September 17, 2012
<u>/s/ Bobby W. Sandage, Jr.</u> Bobby W. Sandage, Jr., Ph.D.	Chief Executive Officer, President and Director (principal executive officer)	September 17, 2012
<u>/s/ Lucy Lu</u> Lucy Lu, M.D.	Chief Financial Officer (principal financial officer)	September 17, 2012
<u>/s/ Dale Ritter</u> Dale Ritter	Senior Vice President, Finance, Chief Accounting Officer (principal accounting officer)	September 17, 2012
<u>/s/ Eric K. Rowinsky</u> Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	September 17, 2012
<u>/s/ David J. Barrett</u> David J. Barrett	Director	September 17, 2012
<u>/s/ Jimmie Harvey, Jr.</u> Jimmie Harvey, Jr., M.D.	Director	September 17, 2012
<u>/s/ J. Jay Lobell</u> J. Jay Lobell	Director	September 17, 2012

<u>/s/ Michael W. Rogers</u> Michael W. Rogers	Director	September 17, 2012
<u>/s/ Lindsay A. Rosenwald</u> Lindsay A. Rosenwald, M.D.	Director	September 17, 2012
<u>Harlan F. Weisman, M.D.</u>	Director	September , 2012



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New York, NY 10154-1895

Direct 212.407.4000
Main 212.407.4000
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September 17, 2012

Coronado Biosciences, Inc.
15 New England Executive Park
Burlington, MA 01803

Re: *Coronado Biosciences, Inc.*

Ladies and Gentlemen:

We have acted as counsel to Coronado Biosciences, Inc., a Delaware corporation (the "Company"), in connection with the authorization of the issuance and sale from time to time, on a delayed basis, in each case as contemplated by the Form S-3 Registration Statement (including the prospectus constituting part thereof (the "Prospectus")) to which this opinion letter has been filed as an exhibit (the "Registration Statement"), by the Company of (i) shares (the "Common Shares") of common stock, par value \$0.001 per share (the "Common Stock"), (ii) shares (the "Preferred Shares") of preferred stock, par value \$0.001 per share (the "Preferred Stock"), (iii) warrants to purchase any Common Stock or Preferred Stock (the "Warrants"), and/or (iv) units consisting of one or more of the foregoing (the "Units"). The Common Shares, Preferred Shares, Warrants and Units are collectively referred to herein as the "Securities." The Securities being registered are for a maximum aggregate offering price of \$75,000,000.00. The Securities may be offered and sold from time to time pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), at which time it is contemplated that the Prospectus will be supplemented in the future by one or more supplements to the Prospectus (each, a "Prospectus Supplement").

We have examined originals or copies, certified or otherwise identified to our satisfaction, of such corporate records of the Company and other certificates and documents of officials of the Company, public officials and others as we have deemed appropriate for purposes of this letter. We have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, and the conformity to authentic original documents of all copies submitted to us as conformed and certified or reproduced copies.

Based upon the foregoing and subject to the assumptions, exceptions, qualifications and limitations set forth hereinafter, we are of the opinion that:

1. The Common Shares (including any Common Shares duly issued upon (i) the exchange or conversion of any Preferred Shares that are exchangeable or convertible into Common Shares or (ii) the exercise of any duly issued Warrants exercisable for Common Shares), upon issuance and delivery of certificates (or book-entry notation if uncertificated) for such Common Shares against payment therefor of such lawful consideration as the Company's Board of Directors (the "Board") (or a duly authorized committee thereof) may determine, will be validly issued, fully paid and non-assessable.

2. The Preferred Shares (including any Preferred Shares duly issued upon (i) the exchange or conversion of any shares of Preferred Stock that are exchangeable or convertible into another series of Preferred Stock or (ii) the exercise of any duly issued Warrants exercisable for Preferred Stock), upon issuance and delivery of certificates (or book-entry notation if uncertificated) for such Preferred Shares against payment therefor of such lawful consideration as the Board (or a duly authorized committee thereof) may determine, will be validly issued, fully paid and non-assessable.

3. The Warrants and the Units, upon issuance and delivery of certificates (or book-entry notation if uncertificated) for such Securities against payment therefor of such lawful consideration as set forth in the Registration Statement, Prospectus or a Prospectus Supplement, will be validly issued and constitute valid and legally binding obligations of the Company.

In rendering the foregoing opinions, we have assumed that: (i) the Registration Statement, and any amendments thereto, shall have become effective under the Securities Act and will remain effective at the time of issuance of any Securities thereunder; (ii) a Prospectus Supplement describing each class or series of Securities offered pursuant to the Registration Statement, to the extent required by applicable law and relevant rules and regulations of the Securities and Exchange Commission (the "Commission"), will be timely filed with the Commission; (iii) the Company will issue and deliver the Securities in the manner contemplated by the Registration Statement, the Prospectus, the applicable Prospectus Supplement and any applicable underwriting agreement; and (iv) all Securities will be issued in compliance with applicable federal and state securities laws.

With respect to the Common Shares, Units and Securities convertible into or exercisable for Common Shares, we have assumed that, at the time of issuance and sale, a sufficient number of shares of Common Stock are authorized and available for issuance under the Company's Certificate of Incorporation as then in effect and that the consideration for the issuance and sale of the Common Shares (including the issuance of Common Shares upon exercise or conversion, as applicable, of the Preferred Shares, Warrants or any Units of such Securities) is in an amount that is not less than the par value of the Common Stock.

With respect to our opinion as to the Preferred Shares, Units and Securities convertible into or exercisable for Preferred Shares, we have assumed that, at the time of issuance and sale, a sufficient number of shares of Preferred Stock are authorized, designated and available for issuance and that the consideration for the issuance and sale of the Preferred Shares (including the issuance of Preferred Shares upon exercise of conversion, as applicable, of Warrants or any Units of such Securities) is in an amount that is not less than the par value of the Preferred Stock. We have also assumed that any Units offered under the Registration Statement, and the related Unit Agreement, will be executed in the forms filed as exhibits to the Registration Statement or incorporated by reference therein.

With respect to any Securities consisting of Warrants, we have further assumed that (i) such Warrants shall have been issued pursuant to a warrant agreement approved by us (individually, a "Warrant Agreement") between the Company and a warrant agent to be identified in the applicable Prospectus Supplement (the "Warrant Agent"); (ii) such Warrant Agreement shall have been duly authorized, executed and delivered on behalf of the Company; (iii) such Warrant Agreement shall be governed by the internal laws of the State of New York, (iv) all terms of such Warrants shall have been established in accordance with the provisions of such Warrant Agreement(s); (v) such Warrants shall have been duly executed, issued and delivered in accordance with the provisions of such Warrant Agreement(s); (vi) such Warrants and the related Warrant Agreement(s), as executed and delivered, do not violate any law applicable to the Company or result in a default under or breach of any agreement or instrument binding upon the Company; and (vii) such Warrants and the related Warrant Agreement(s), as executed and delivered, comply with all requirements and restrictions, if any, applicable to the Company, in any case whether imposed by any court or governmental or regulatory body having jurisdiction over the Company.

To the extent that the obligations of the Company under any Warrant or Warrant Agreement may be dependent on such matters, we further have assumed for purposes of this opinion that the Warrant Agent under each Warrant Agreement at the time of the execution of such Warrant Agreement (i) is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization; (ii) is duly qualified to engage in the activities contemplated by such Warrant Agreement; (iii) has duly authorized, executed and delivered such Warrant Agreement, and such Warrant Agreement constitutes the legally valid and binding obligation of such Warrant Agent, enforceable against such Warrant Agent in accordance with its terms; (iv) is in compliance, with respect to acting as a Warrant Agent under such Warrant Agreement, with all applicable laws and regulations; and (v) has the requisite organizational and legal power and authority to perform its obligations under such Warrant Agreement.

The opinions set forth above are subject to the following exceptions, limitations and qualifications: (i) the effect of bankruptcy, insolvency, reorganization, arrangement, moratorium, fraudulent conveyance, fraudulent transfer and other similar laws relating to or affecting the rights of creditors, (ii) the effect of general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing and the possible unavailability of specific performance, injunctive relief and other equitable remedies), regardless of whether considered in a proceeding at law or in equity, and (iii) the effect of public policy considerations that may limit the rights of the parties to obtain further remedies.

We express no opinion with respect to the enforceability of: (i) provisions relating to choice of law, choice of venue, jurisdiction or waivers of jury trial, or (ii) any waiver of any usury defense. This opinion letter is rendered as of the date hereof, and we disclaim any undertaking to advise you of any subsequent changes in the facts stated or assumed herein or any subsequent changes in applicable law that may come to our attention, and we have assumed that no change in the facts stated or assumed herein or in applicable law after the date hereof will affect adversely our ability to render an opinion letter after the date hereof (i) containing the same legal conclusions set forth herein and (ii) subject only to such (or fewer) assumptions, limitations and qualifications as are contained herein.

The opinions we express above are based upon a review only of those laws, statutes, rules, ordinances and regulations which, in our experience, a securities lawyer who is a member of the bar of the State of New York and practicing before the Commission exercising customary professional diligence would reasonably recognize as being applicable to the foregoing transactions. While certain members of this firm are admitted to practice in certain jurisdictions other than New York, in rendering the foregoing opinions we have not examined the laws and we do not express any opinion herein concerning any laws other than the internal laws of the State of New York and the Delaware General Corporation Law or consulted with members of this firm who are admitted in any other jurisdictions other than New York with respect to the laws of any other jurisdiction. Accordingly, the opinions we express herein are limited to matters involving the internal laws of the State of New York and the Delaware General Corporation law.

This opinion has been prepared solely for use in connection with the transmitting for filing of the Registration Statement on the date of this opinion and may be relied upon for no other purpose without our prior written consent.

We hereby consent to the filing of this opinion letter with the Commission as Exhibit 5.1 to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act and to the reference to our firm therein and in the Prospectus and any Prospectus Supplement under the caption "Legal Matters." In giving such consent, we do not thereby admit that this firm is within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission under such Section.

Very truly yours,

/s/ Loeb & Loeb LLP

Loeb & Loeb LLP

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in this Registration Statement on Form S-3 of our report dated March 29, 2012 relating to the consolidated financial statements, which appears in Coronado Biosciences, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2011. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
September 17, 2012