

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

**POST-EFFECTIVE AMENDMENT NO. 1
ON FORM S-3 TO
FORM S-1
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:

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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

EXPLANATORY NOTE

This Post-Effective Amendment No. 1 on Form S-3 to Form S-1 contains an updated prospectus relating to the resale, from time to time, of up to 5,475,316 shares of our common stock, par value \$.001 per share, being offered by the selling stockholders identified in this prospectus, all of which were initially registered for resale on our registration statement on Form S-1 (File No. 333-177041) declared effective by the Securities and Exchange Commission on November 15, 2011. All filing fees payable in connection with the registration of these securities were previously paid in connection with the filing of the original registration statement.

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The information in this prospectus is not complete and may be changed. The selling stockholders 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, OCTOBER 1, 2012

PRELIMINARY PROSPECTUS



5,475,316 shares of common stock

This prospectus relates to the resale, from time to time, of up to 5,475,316 shares of our common stock, par value \$.001 per share, being offered by the selling stockholders identified in this prospectus, including 834,095 shares issuable upon exercise of outstanding warrants, or the Warrants.

We will not receive any of the proceeds from the sale of the shares by the selling stockholders. To the extent the Warrants are exercised for cash, if at all, we will receive the exercise price for the Warrants. The selling stockholders may sell the shares as set forth herein under "Plan of Distribution."

We have agreed to pay certain expenses in connection with the registration of the shares.

Our common stock is listed on the NASDAQ Capital Market under the symbol "CNDO." On September 27, 2012, the last reported sale price of our common stock on the NASDAQ Capital Market was \$5.54.

Investing in our securities involves a high degree of risk. You should carefully consider the [risk factors](#) beginning on page 3 of this prospectus before purchasing shares of our common stock.

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

The date of this prospectus is _____, 2012

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 Securities and Exchange Commission, or SEC, including in our Quarterly Report on Form 10-Q, which we filed with the SEC on August 8, 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. 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.

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.

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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.

The Offering

Common stock being offered by selling stockholders 5,475,316 shares ⁽¹⁾

Common stock outstanding 24,375,749 shares ⁽²⁾

Use of Proceeds We will not receive any proceeds from the sale of the shares by the selling stockholders. However, to the extent that the Warrants are exercised for cash, we will receive proceeds from any exercise of the Warrants up to an aggregate of approximately \$2.6 million. We intend to use any proceeds received from the exercise of the Warrants for working capital and other general corporate purposes.

NASDAQ Capital Market symbol CNDO

Risk Factors The securities offered by this prospectus are speculative and involve a high degree of risk and investors purchasing securities should not purchase the securities unless they can afford the loss of their entire investment. See "Risk Factors" beginning on page 3.

⁽¹⁾ Includes 834,095 shares underlying the Warrants.

⁽²⁾ Shares outstanding as of September 28, 2012.

RISK FACTORS

Investing in our securities involves risk. Before making an investment decision, you should carefully consider the following risk factors as well as 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, 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.

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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.

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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-

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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.

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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.

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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.

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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

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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

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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.

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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.

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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. In addition, we recently filed a shelf registration statement on Form S-3 pursuant to which we may sell up to \$75 million of our equity securities over the next three years. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

We 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.

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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, 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 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 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 and any document incorporated herein by reference, and particularly our forward-looking statements, by these cautionary statements.

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USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares being offered by the selling stockholders. However, to the extent that the Warrants are exercised for cash, we will receive proceeds from any exercise of the Warrants up to an aggregate of approximately \$2.6 million. We intend to use any proceeds received from the exercise of the Warrants for working capital and other general corporate purposes.

DESCRIPTION OF SECURITIES

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 28, 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 28, 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.

Following the date of this prospectus, our board of directors is empowered, without stockholder approval, to issue shares of preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. The preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us. Although we do not currently intend to issue any shares of preferred stock, we cannot assure you that we will not do so in the future.

SELLING STOCKHOLDERS

We are registering for resale shares of our common stock (i) issued on November 15, 2011 upon automatic conversion of preferred stock; (ii) issued as a dividend to holders of preferred stock; and (iii) issuable upon the exercise of Warrants held by the selling stockholders identified below.

The shares of common stock are being registered pursuant to registration rights granted to the holders of the preferred stock and Warrants in a series of private placements in which such securities were issued. The preferred stock was issued in a series of private placements to accredited investors. With the exception of the Warrants issued to Paramount Credit Partners, LLC, or PCP, the Warrants were originally issued as compensation to the placement agents for their services in connection with such offerings. The following sets forth information regarding such private placements:

- Between April and August 2010, we issued an aggregate of 4,357,885 shares of Series A Convertible Preferred Stock, or Series A shares, at a purchase price of \$8.39 per share to an aggregate of 269 accredited investors, which amount includes shares that were issued upon the conversion of outstanding indebtedness. Paramount BioCapital, Inc., or PBC, acted as placement agent in connection with the Series A financing, as well as the original debt financings, and received warrants to purchase an aggregate of 348,644 shares of common stock. On May 20, 2011, we issued 2,178,917 shares of common stock as a dividend to the holders of the Series A shares.
- In connection with the issuance of the PCP bridge notes in 2009, we issued warrants to PCP to purchase an aggregate of 40,787 shares of common stock at an exercise price of \$6.15 per share.
- In January 2011, in connection with the acquisition of the CNDO-201 assets, we issued 2,525,667 shares of Series B Convertible Preferred Stock, or Series B shares, to Asphelia Pharmaceuticals, Inc., or Asphelia. All of such Series B shares were subsequently distributed to the preferred stockholders of Asphelia.
- Between May and June 2011, we issued an aggregate of 4,612,624 shares of Series C Convertible Preferred Stock, or Series C shares, at a purchase price of \$5.59 per share to an aggregate of 343 accredited investors. National acted as placement agent in connection with the Series C financing and received warrants to purchase an aggregate of 461,263 shares of common stock.

We are registering the shares to permit the selling stockholders and their pledgees, donees, transferees and other successors-in-interest that receive their shares from a selling stockholder as a gift, partnership distribution or other non-sale related transfer after the date of this prospectus to resell the shares when and as they deem appropriate in the manner described in the "Plan of Distribution." The following selling stockholder table sets forth:

- the name of the selling stockholders,
- the number and percentage of shares of our common stock that the selling stockholders owned as of the date of this prospectus prior to the offering for resale of the shares under this prospectus,
- the maximum number of shares of our common stock that may be offered for resale for the account of the selling stockholders under this prospectus, and
- the number and percentage of shares of our common stock to be owned by the selling stockholders after the offering of the shares (assuming all of the offered shares are sold by the selling stockholders).

Except for Bobby W. Sandage, Jr., Ph.D., Lindsay A. Rosenwald, M.D., Glenn L. Cooper, M.D. and Dale Ritter, none of the selling stockholders has been an officer or director of the Company or any of its predecessors or affiliates within the last three years. Except for the aforementioned individuals, no selling stockholder had a material relationship with us within the last three years other than National, which served as placement agent for the Series C financing and an underwriter in our June 2012 public offering, and Timothy Hofer, a consultant.

Except for National, Bishop Rosen & Co., Inc., CIM Securities, Inc., Cresta Capital Strategies, LLC, Emerson Equity LLC, Maxim Partners, LLC, Network 1 Financial Securities Inc. and Summer Street Research Partners, none of the selling stockholders is a broker dealer. All of such entities received the Warrants exercisable for the shares they are offering for resale in

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this prospectus as placement agent compensation. National distributed certain of the warrants it received to its designees as indicated in the footnotes to the table below. In addition, PBC, which acted as placement agent for our private placements of notes issued in 2008 and 2009, as well as our Series A shares, distributed all of the Warrants it received as placement agent compensation to its designees listed as selling stockholders in such table. Such individuals may be deemed an affiliate of a broker dealer, as indicated in the footnotes to the table.

Other than the individuals to whom Warrants were transferred by National and PBC, none of the selling stockholders is an affiliate of a broker dealer except for Lindsay A. Rosenwald, Paramount Biosciences, LLC, PCP, Capretti Grandi, LLC and LAR Family Trusts. Each of Lindsay A. Rosenwald, Paramount Biosciences, LLC, PCP, Capretti Grandi, LLC and LAR Family Trusts certified to us that it or he bought the securities for its or his own account and at the time of purchase, it or he had no agreements or understandings, directly or indirectly, with any person to distribute the securities. To our knowledge, none of the selling stockholders has any agreement or understanding to distribute any of the shares being registered.

Unless otherwise indicated in the footnotes to the table below, the shares of common stock being registered on behalf of the selling stockholders identified below hereunder are issuable upon the exercise of Warrants held by such selling stockholders.

<u>Name of Selling Stockholder</u>	<u>Common Stock Owned Prior to Offering (1)</u>	<u>Maximum Number of Shares of Common Stock to be Sold</u>	<u>Number of Shares of Common Stock Owned After Offering</u>	<u>Percentage Ownership Prior to Offering</u>	<u>Percentage Ownership After Offering</u>
Aquino, Albert (27)	0	322	0	0	0
Arnsman, Michael (27)	0	74	0	0	0
Auerbach, Jeffrey (27)	0	488	0	0	0
Axel, Eric (27)	0	698	0	0	0
Babekov, Oleg Alex (27)	0	1,055	0	0	0
Beechwood Ventures LLC (2)	0	453	0	0	0
Bianco, Donald (27)	0	1,071	0	0	0
Bishop Rosen & Co., Inc. (3)	0	1,207	0	0	0
Bookbinder, Robert (27)	0	38	0	0	0
Brentwood Properties, LLC (4)	0	453	0	0	0
Brewer, Jack	0	3,429	0	0	0
Brissi, Benjamin	0	9,073	0	0	0
Brookline Coronado Investment Fund LLC (1) (5)	1,352,825	457,687	895,138	5.5%	3.7%
Bruscianelli, Jack (27)	0	136	0	0	0
Bruscianelli, Mark (27)	0	147	0	0	0
Burkoff, Mike	0	818	0	0	0
Burnham, John (27)	0	4,791	0	0	0
CSA Biotechnology Fund I, LLC (1) (5)	1,352,825	35,757	1,317,068	5.5%	5.4%
CSA Biotechnology Fund II, LLC (1) (5)	1,352,825	559,381	793,444	5.5%	3.3%
Capretti Grandi, LLC (1) (6)	170,983	170,983	0	*	0
Carlo, Dom (27)	0	858	0	0	0
Cassella, Annette (27)	0	2,500	0	0	0
Chavous, Corey L.	0	3,284	0	0	0
CIM Securities, Inc. (7)	0	3,374	0	0	0
Claps, Dan (27)	0	3,000	0	0	0
Clay, Nate (27)	0	4,441	0	0	0
Cohen, Brian Todd (27)	0	414	0	0	0
Cooper, Glenn Lawrence (1)	40,000	30,000	10,000	*	*
Coviello, Lara (27)	0	589	0	0	0
Cresta Capital Strategies, LLC (8)	0	999	0	0	0
D'Albora, Vincent (27)	0	2,500	0	0	0
Defex, Damian (27)	0	735	0	0	0
Devary, James (27)	0	625	0	0	0
Dimartini, Frank (27)	0	11,005	0	0	0
Drekou, Ken (27)	0	735	0	0	0
Edmonds, James P.	0	4,529	0	0	0
Ehrhardt, Jennifer	0	32,415	0	0	0
Eichner, James (27)	0	640	0	0	0
Elliot Associates LP (1) (9)	792,328	178,890	613,438	3.3%	2.5%
Elliot International LP (1) (9)	1,654,898	268,336	1,386,562	6.8%	5.7%
Emerson Equity LLC (10)	0	269	0	0	0

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<u>Name of Selling Stockholder</u>	<u>Common Stock Owned Prior to Offering (1)</u>	<u>Maximum Number of Shares of Common Stock to be Sold</u>	<u>Number of Shares of Common Stock Owned After Offering</u>	<u>Percentage Ownership Prior to Offering</u>	<u>Percentage Ownership After Offering</u>
Figueroa, Adam (27)	0	694	0	0	0
Friedman, Adam (27)	0	2,888	0	0	0
Gebron, Joseph (27)	0	3,000	0	0	0
Ghazi-Zadeh, Kaywan (27)	0	450	0	0	0
Goldstein, Mark (27)	0	9,348	0	0	0
Haddad, Coby (27)	0	1,071	0	0	0
Haggerty, Ed (27)	0	269	0	0	0
Hechler, Glenn (27)	0	11,031	0	0	0
Hegener, Paul	0	453	0	0	0
Hofer, Timothy	0	123,053	0	*	*
Holly, John T. (27)	0	574	0	0	0
James, Eric (27)	0	23,600	0	0	0
Jones, Chris (27)	0	976	0	0	0
Jones, Stephen (27)	0	450	0	0	0
Kanter Family Foundation (11)	0	226	0	0	0
Karjanis, Dennis (27)	0	747	0	0	0
Katzmann, Scott	20,000	3,980	20,000	*	*
Kelly, Thomas (27)	0	3,987	0	0	0
Klein, David (27)	0	3,286	0	0	0
Kurland, Scott	0	739	0	0	0
LAR Family Trusts (1) (12)	453,822	135,389	318,433	1.9%	1.3%
Leba Investments LP (13)	0	679	0	0	0
LeDoux, David (27)	0	1,147	0	0	0
Lindsay A. Rosenwald, MD 2000 Family Trust (1) (14)	720,000	325,793	394,207	3.0%	1.6%
Lobell, J. Jay	0	2,265	0	0	0
Lukack, Matt (27)	0	100	0	0	0
Lydon, Harris	0	53,080	0	0	0
Lyon, Eric (27)	0	574	0	0	0
Mamias, Peter (27)	0	119	0	0	0
Manchester Securities Corp. (1) (9)	1,284,053	1,284,053	0	5.3%	0
Martin, Jeremy (27)	0	652	0	0	0
Mathews, Phil (27)	0	652	0	0	0
Maxim Partners LLC (15)	0	49,040	0	0	0
McDowell, Clemm (27)	0	122	0	0	0
McQuade, Declan (27)	0	80	0	0	0
Medeck, James (27)	0	1,800	0	0	0
Medeck, Keith (27)	0	13,946	0	0	0
Millstone, Robert D.	0	2,243	0	0	0
Monteforte, Roger (27)	0	20,176	0	0	0
Mullen, Michael (27)	0	68,501	0	0	0
National Securities Corporation (16)	0	158,012	0	0	0
Network 1 Financial Securities Inc. (17)	0	3,750	0	0	0
Opus Point Partners LLC (18) (27)	0	80,783	0	0	0
Pacific Speed LLC (19)	0	453	0	0	0
Paramount Biosciences, LLC (1) (6)	742,861	742,861	0	3.0%	0
Phan, Peter (27)	0	1,389	0	0	0
Phillips, Ron	0	340	0	0	0
Plunkett, Stephen (27)	0	337	0	0	0
Rapczyk, Eric (27)	0	178	0	0	0
Reed, Ryan (27)	0	450	0	0	0
Rhee, Joon (27)	0	14,363	0	0	0
Rich, David (27)	0	68	0	0	0
Rich, Jonathan C. (27)	0	22,745	0	0	0
Ritter, Dale and Debra (1) (20)	10,000	5,000	5,000	*	*
Rosenwald, Lindsay A. (1) (20)	2,659,001	444,451	2,214,550	10.9%	9.1%
San Pedro, Ray (27)	0	4,119	0	0	0
Sandage Jr., Ph.D., Bobby W. (1) (20)	21,500	10,000	11,500	*	*
Schechner, Matthew Bruce (27)	0	621	0	0	0
Schiavello, Michael (27)	0	285	0	0	0
Sever, Nogay (27)	0	1,500	0	0	0
Shames, Scott (27)	0	488	0	0	0
Soernaya, Edwin (27)	0	450	0	0	0
Spiegel, Robert	0	309	0	0	0
Spinelli, Anthony (27)	0	200	0	0	0
Starlight Investment Holdings, Ltd. (21)	0	2,265	0	0	0

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<u>Name of Selling Stockholder</u>	<u>Common Stock Owned Prior to Offering (1)</u>	<u>Maximum Number of Shares of Common Stock to be Sold</u>	<u>Number of Shares of Common Stock Owned After Offering</u>	<u>Percentage Ownership Prior to Offering</u>	<u>Percentage Ownership After Offering</u>
Summer Street Research Partners (22) (27)	0	1,922	0	0	0
Takos, Bill (27)	0	285	0	0	0
Tempesta, Peter (27)	0	173	0	0	0
Tennett, Andrew (27)	0	46	0	0	0
The Jack and LeAnne Miller Family Trust (23)	0	566	0	0	0
The Sarazin Company, Inc. Profit Sharing Plan (24)	0	453	0	0	0
Tisu Investment Ltd. (25)	0	2,264	0	0	0
Troccoli, Carmelo E (27)	0	12,214	0	0	0
Vandress, Josh (27)	0	3,264	0	0	0
Veraison BioFund GP, LLC (26)	0	1,132	0	0	0
Walker, Wayde (27)	0	4,441	0	0	0
Warren, James (27)	0	343	0	0	0
Welling, Justin	0	476	0	0	0
Zalatimo, Russell (27)	0	2,888	0	0	0

* Less than one percent.

- (1) Represents the number of shares of our common stock that the selling stockholder owns as of the date of this prospectus but does not give effect to exercise of the Warrants or any other warrants or options. For the beneficial ownership of our officers, directors and principal stockholders, please see “Security Ownership of Certain Beneficial Owners and Management” incorporated by reference into this prospectus from our Definitive Proxy Statement on Schedule 14A filed with the SEC on July 13, 2012.
- (2) Ruki Renov has voting and dispositive power over the shares held by Beechwood Ventures LLC.
- (3) Isaac Schlesinger has voting and dispositive power over the shares held by Bishop Rosen & Co.
- (4) Jonah Bruck has voting and dispositive power over the shares held by Brentwood Properties, LLC.
- (5) Represents shares of common stock issued upon automatic conversion of preferred stock and owned collectively by Brookline Coronado Investment Fund LLC, CSA Biotechnology Fund I, LLC and CSA Biotechnology Fund II LLC. Rainer Twiford has voting and dispositive power over the shares held by these entities. The address of these entities is c/o Brookline Investments, Inc., 2501 Twentieth Place South, Suite 275, Birmingham, AL 35223.
- (6) Represents shares of common stock issued upon automatic conversion of preferred stock. Lindsay A. Rosenwald has voting and dispositive power over the shares held by Capretti Grandi, LLC and Paramount Biosciences, LLC.
- (7) Patrick Adams, CFA has voting and dispositive power over the shares held by CIM Securities, Inc.
- (8) Abraham Mirman has voting and dispositive power over the shares held by Cresta Capital Strategies, LLC.
- (9) Represents shares of common stock issued upon automatic conversion of preferred stock. Mr. Paul E. Singer has voting and dispositive power over the shares held by Elliot Associates LP, Elliot International LP and Manchester Securities Corp.
- (10) Dominic Baldini has voting and dispositive power over the shares held by Emerson Equity LLC.
- (11) Joel Kanter has voting and dispositive power over the shares held by Kanter Family Foundation.

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- (12) 128,029 of such shares represents shares of common stock issued upon automatic conversion of preferred stock. Maryellen V. McLarnon has voting and dispositive power over the shares held by LAR Family Trusts.
- (13) Elliot Hahn has voting and dispositive power over the shares held by Leba Investments LP.
- (14) Represents shares of common stock issued upon automatic conversion of preferred stock. Maryellen V. McLarnon has voting and dispositive power over the shares held by the Lindsay A. Rosenwald, MD 2000 Family Trust.
- (15) Michael Rabinowitz has voting and dispositive power over the shares held by Maxim Partners LLC.
- (16) Mark Goldwasser has voting and dispositive power over the shares held by National Securities Corporation.
- (17) William Hunt has voting and dispositive power over the shares held by Network 1 Financial Securities Inc.
- (18) Alan Levin has voting and dispositive power over the shares held by Opus Point Financial LLC.
- (19) P. Joseph Hegener, Jr. and Nicholas Esayian share voting and dispositive power over the shares held by Pacific Speed LLC.
- (20) Represents shares of common stock issued upon automatic conversion of preferred stock.
- (21) David George Jenner and Nicole Marguerite Hodge share voting and dispositive power over the shares held by Starlight Investment Holdings Limited.
- (22) Harris Lydon has voting and dispositive power over the shares held by Summer Street Research Partners.
- (23) Jack Miller has voting and dispositive power over the shares held by The Jack and LeAnne Miller Family Trust.
- (24) P. Joseph Hegener, Jr. and Jerry Sarazin share voting and dispositive power over the shares held by The Sarazin Company, Inc. Profit Sharing Plan.
- (25) Tis Prager has voting and dispositive power over the shares held by Tisu Investment Ltd.
- (26) P. Joseph Hegener, Jr. and Robert P. Baizer share voting and dispositive power over the shares held by Veraison BioFund GP, LLC.
- (27) Such selling stockholder is an affiliate of National and received the Warrants as placement agent compensation.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issuable upon conversion of preferred stock, issued as a dividend to the holders of preferred stock and upon exercise of Warrants issued to the selling stockholders to permit the resale of these shares of common stock by the holders from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of

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the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and if such short sale shall take place after the date that this Registration Statement is declared effective by the SEC, the selling stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered on this registration statement to cover short sales of our common stock made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the SEC.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer or agents participating in the distribution of the shares of common stock may be deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the shelf registration statement, of which this prospectus forms a part.

Each selling stockholder and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, including, without limitation, SEC filing fees and expenses of compliance with state securities or “blue sky” laws; provided, however, that each selling stockholder will pay all underwriting discounts and selling commissions, if any and any related legal expenses incurred by it. We will indemnify the selling stockholders against certain liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholders specifically for use in this prospectus, in accordance with the related registration rights agreements, or we may be entitled to contribution.

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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, August 29, 2012 and September 25, 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 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.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different or additional information. If such information is provided to you, you should not rely on it. This prospectus is not an offer of these securities in any jurisdiction where an offer and sale is not permitted.



5,475,316 shares of common stock

PROSPECTUS

, 2012

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PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the various expenses, all of which will be borne by the registrant, in connection with the sale and distribution of the securities being registered, other than the underwriting discounts and commissions. All amounts shown are estimates except for the SEC registration fee.

SEC registration fee	\$ 5,569
Accounting fees and expenses	\$ 25,000
Legal fees and expenses	\$185,000
Miscellaneous	\$ 20,000

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

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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.

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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>
4.1	Form of Common Stock Certificate.(1)
4.2	Form of Series A Convertible Preferred Stock Certificate.(1)
4.3	Form of Series B Convertible Preferred Stock Certificate.(1)
4.4	Form of Series C Convertible Preferred Stock Certificate.(1)
4.5	Form of Warrant to Purchase Common Stock issued by the Registrant in connection with the 2008 bridge financing.(1)
4.6	Form of Warrant to Purchase Common Stock issued by the Registrant in connection with the 2009 bridge financing.(1)
4.7	Form of Warrant to Purchase Common Stock issued by the Registrant in connection with the Series A financing.(1)
4.8	Form of Warrant to Purchase Series C Convertible Preferred Stock issued by the Registrant in connection with the 2011 Series C financing.(1)
4.9	Form of Consultant/Agent Warrant to Purchase Common Stock.(1)
5.1	Opinion of Loeb & Loeb LLP re: legality.(2)
23.1*	Consent of PricewaterhouseCoopers LLP.
23.2	Consent of Loeb & Loeb LLP (included in Exhibit 5.1).(2)
24.1	Power of Attorney (included on signature page).

* Filed herewith.

- (1) Filed as an exhibit with the same number to the Registrant's Registration Statement on Form 10-12G (File No. 000-54463) initially filed on July 15, 2011.
- (2) Filed as an exhibit with the same number to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-177041) filed on November 14, 2011.

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;

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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.

(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.

(4) That for the purpose of determining any liability under the Securities Act of 1933 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

(b) The undersigned hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

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

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

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

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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 this Post-Effective Amendment No. 1 on Form S-3 to Form S-1 and has duly caused this Post-Effective Amendment No. 1 on Form S-3 to Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Burlington, State of Massachusetts, on the 1st day of October, 2012.

CORONADO BIOSCIENCES, INC.

By: /s/ Bobby W. Sandage, Jr.
Name: Bobby W. Sandage, Jr., Ph.D.
Title: Chief Executive Officer

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
* <u>Glenn L. Cooper, M.D.</u>	Executive Chairman of the Board of Directors	October 1, 2012
<u>/s/ Bobby W. Sandage, Jr.</u> Bobby W. Sandage, Jr., Ph.D.	Chief Executive Officer, President and Director (principal executive officer)	October 1, 2012
* <u>Lucy Lu, M.D.</u>	Chief Financial Officer (principal financial officer)	October 1, 2012
<u>/s/ Dale Ritter</u> Dale Ritter	Senior Vice President, Finance, Chief Accounting Officer (principal accounting officer)	October 1, 2012
* <u>Eric K. Rowinsky, M.D.</u>	Vice Chairman of the Board of Directors	October 1, 2012
* <u>David J. Barrett</u>	Director	October 1, 2012
* <u>Jimmie Harvey, Jr., M.D.</u>	Director	October 1, 2012
* <u>J. Jay Lobell</u>	Director	October 1, 2012
* <u>Michael W. Rogers</u>	Director	October 1, 2012
* <u>Lindsay A. Rosenwald, M.D.</u>	Director	October 1, 2012
<u>Harlan F. Weisman, M.D.</u>	Director	October , 2012

* By: Dale Ritter, as attorney-in-fact

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
October 1, 2012