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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended: December 31, 2014

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from to

Commission File No. 001-35366

CORONADO BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-5157386**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
24 New England Executive Park, Suite 105 Burlington , MA	**01803**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 652-4500

Securities registered pursuant to Section 12(b) of the Act:

(Title of Class)	**(Name of exchange on which registered)**
Common Stock, par value $0.001 per share	**NASDAQ Capital Market**

Securities registered pursuant to section 12(g) of the Act:
None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter: $76,216,972 based upon the closing sale price of our common stock of $1.72 on that date. Common stock held by each officer and director and by each person known to own in excess of 5% of outstanding shares of our common

stock has been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status in not necessarily a conclusive determination for other purposes.

As of March 13, 2015, there were 46,498,545 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2015 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2015 are incorporated by reference into Part III hereof.

CORONADO BIOSCIENCES, INC.
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. Factors that could cause actual results to differ materially from those currently anticipated include those set forth under "Item 1A. Risk Factors" including, in particular, risks relating to:

- our growth strategy;
- our ability to identify, acquire, close and integrate product targets successfully and on a timely basis;
- our ability to attract, integrate and retain key personnel;
- financing and strategic agreements and relationships;
- our need for substantial additional funds and uncertainties relating to financings;
- the early stage of products under development;
- the results of research and development activities;
- uncertainties relating to preclinical and clinical testing;
- our ability to secure and maintain third-party manufacturing, marketing and distribution of our products;
- government regulation;
- patent and intellectual property matters;
- dependence on third-party manufacturers; and
- competition.

We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

PART I

Item 1. Business.

Overview

Since inception on June 28, 2006, Coronado Biosciences, Inc., incorporated in Delaware, has been involved in the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer, namely CNDO-201 or *Trichuris suis* ova ("TSO") and CNDO-109, as more fully described below. As part of our growth strategy, we have commenced and will continue to leverage our substantial biopharmaceutical business, financial and drug-development expertise to invest in the acquisition, development and commercialization of novel pharmaceutical and other biomedical products. We are employing a variety of approaches and corporate structures to acquire rights to and finance a diverse portfolio of innovative pharmaceutical and biotechnology products, technologies and companies. These may include licensing, partnerships, joint ventures, and private or public spin-outs. We believe these activities will diversify our product development and, over time, may enhance shareholder value through potential royalty, milestone and equity payments and fees as well as potential product revenues.

Business Strategy

Our approach is designed for maximum flexibility, allowing us to invest in a broad array of new technologies with clinical and commercial potential. It enables us to move quickly to take advantage of time-sensitive opportunities when necessary, and provides us with a range of options that allow us to select what we believe is the most advantageous corporate or financial structure for each candidate for investment. Over time, our novel approach is also expected to provide opportunities to achieve synergies across some of our investment assets. As we seek to acquire and advance investment opportunities with high growth potential, we are also exploring strategic options to realize value from our existing product candidates, TSO and CNDO-109. We expect to report progress with these initiatives going forward.

Recent Events

We made significant progress in implementing our new growth strategy in 2014. At the end of the year, the Company had several subsidiaries involved in a number of therapeutic areas, such as products for immunological diseases, cancer and dermatology. These subsidiaries include, for example, CB Securities Corporation, Innmune Limited, Coronado SO Co., Inc. ("Coronado SO"), Cyprium, Inc., Altamira Bio Inc. and Journey Medical Corporation ("JMC").

During the second half of 2014, we formed JMC to acquire and license dermatology products focused on acne, steroid responsive dermatoses, pigmentation and antifungals for promotion to dermatologists and pediatricians. In addition, we formed a blank check company in the Cayman Islands, CB Pharma Acquisition Corp. ("CB Pharma"), for the purpose of entering into a business combination with one or more businesses or entities, with a current focus in the specialty pharmaceuticals and generic drug industries, among others. In December 2014, CB Pharma closed its initial public offering ("IPO"), including an over-allotment exercise, and a private placement raising net proceeds of $42.9 million, to be held in trust until such time that a business combination is consummated.

On January 14, 2015, our subsidiary Coronado SO, entered into an exclusive license agreement with a third party for a license for a Phase 2, topical product, 1UO, used in the treatment of Hand-Foot Syndrome, a common painful side effect of chemotherapeutics. To purchase the license, Coronado SO paid $0.9 million upfront and will pay an additional $0.9 million nine months from the execution date of the license. Additional payments are due upon the achievement of certain development milestones and royalties and will become due on sales of the product.

On February 18, 2015, we purchased an exclusive license to an intravenous ("IV") formulation of Tramadol for the U.S. market from Revogenex Ireland Ltd ("Revogenex"), a privately held company in Dublin, Ireland. We made an upfront payment of $2.0 million to Revogenex upon execution of the exclusive license and Revogenex is eligible to receive additional milestone payments upon the achievement of certain development milestones, in addition to royalty payments for sales of the product. Tramadol is a centrally acting synthetic opioid analgesic for moderate to moderately severe pain and is available as immediate-release or extended-release tablets in the United States. In connection with this purchase, we formed a subsidiary, Avenue Therapeutics, Inc. ("Avenue Therapeutics"), to acquire, in-license, develop and commercialize products principally for use in the U.S. hospital market. We intend to transfer the Revogenex license to Avenue Therapeutics. Avenue Therapeutics plans to initiate a Phase III development program of IV Tramadol for the management of post-operative pain later this year. Under the terms of our agreement with Avenue Therapeutics, we and Avenue Therapeutics will assume sole responsibility for the development and commercialization of IV Tramadol in the United States. Avenue Therapeutics plans to seek additional products to develop in addition to IV Tramadol.

On February 27, 2015, Ovamed GmbH ("Ovamed"), our only supplier and manufacturer of TSO, filed for insolvency in Germany, a process similar to U.S. bankruptcy. At this time, we are unable to assess the likelihood of Ovamed continuing operations or being able to supply TSO. We have sufficient supply to complete our Phase 2 ASD Study and we are assessing our options with respect to future supply.

On March 4, 2015 we formed a new subsidiary, Checkpoint Therapeutics, Inc. ("Checkpoint"), to develop a portfolio of fully human immuno-oncology targeted antibodies generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a professor in the Department of Cancer Immunology and AIDS at the Dana-Farber Cancer Institute ("Dana-Farber"). Dr. Marasco will chair the Scientific Advisory Board of Checkpoint. Under the terms of the agreement, Checkpoint will pay Dana-Farber an up-front licensing fee in addition to development and sales-based milestone payments and royalties on net sales. The portfolio of antibodies licensed from Dana-Farber includes antibodies targeting PD-L1, GITR and CAIX. Checkpoint plans to develop these novel immuno-oncology and checkpoint inhibitor antibodies on its own and in combination with each other, as data suggests that combinations of these targets can work synergistically. Clinical trials are expected to start in the second half of next year. In connection with the license agreement with Dana-Farber, Checkpoint entered into a collaboration agreement with TG Therapeutics, Inc. ("TGTX") to develop and commercialize the Anti-PD-L1 and Anti-GITR antibody research programs in the field of hematological malignancies. Checkpoint retains the right to develop and commercialize these antibodies in solid tumors. Both programs are currently in pre-clinical development. Under the terms of the agreement, TGTX will pay Checkpoint an up-front licensing fee as well as make development and sales-based milestone payments and will pay a tiered single digit royalty on net sales.

Journey Medical Corporation

In October 2014, we formed JMC, which focuses on acquiring, developing, licensing, and commercializing branded dermatology products.

JMC is led by President and CEO, Claude Maraoui, who has more than 25 years of experience in commercializing dermatology products. Mr. Maraoui served as Vice President of Dermatology Sales at Medicis Pharmaceuticals, Inc. ("Medicis") and has over 50 product launches during his career. In 2012, Valeant Pharmaceuticals International Inc. ("Valeant") acquired Medicis for approximately $2.6B.

Kevin Wojciechowski is the Director of Marketing & Sales Training for JMC. He joined JMC with 14 years of experience in the pharmaceutical industry. At Medicis and Valeant, Mr. Wojciechowski was responsible for marketing SOLODYN, which during his tenure was the most prescribed branded medication in dermatology. He has also held positions of increasing responsibility in marketing, sales, sales training, and operations for Johnson & Johnson, Cephalon, Inc. and Stryker Corporation.

Andrew Zwible is the Director of Sales Operations for JMC and has 5 years of experience in dermatology pharmaceuticals, working for Medicis and Valeant as a forecasting and analytics expert. Mr. Zwible also assisted with the buy-side $455MM acquisition of Graceway Pharmaceuticals LLC and the sell-side $2.6B acquisition of Medicis. He has previous experience in investment banking and financial analysis.

JMC will primarily focus on the dermatology specialty, competing with companies such as Actavis plc, Aqua Pharmaceuticals, LLC, Galderma S.A., Leo Pharma A/S, Merz Pharma GmbH & Co. KGaA, and Valeant. JMC is headquartered in Scottsdale, AZ.

On March 10, 2015, JMC entered into a license and supply agreement to acquire rights to distribute a generic dermatological product. JMC made an upfront payment of $1,250,000 and will have to pay an additional $750,000 upon receipt of the product. Further payments will be made based on a revenue sharing arrangement.

CB Pharma Acquisition Corp.

In September 2014, we formed a blank check company in the Cayman Islands, CB Pharma, as an exempted Cayman Island company with limited liability. Exempted companies are Cayman Islands companies wishing to conduct business outside the Cayman Islands and, as such, are exempted from complying with certain provisions of the Companies Law. As an exempted company, it applied for and received a tax exemption undertaking from the Cayman Islands government that, in accordance with section 6 of the Tax Concessions Law (2011 Revision) of the Cayman Islands, for a period of 20 years from the date of the undertaking, no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciations shall apply to us or our operations and, in addition, that no tax to be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable (i) on or in respect of our shares, debentures or other obligations or (ii) by way of the withholding in whole or in part of a payment of dividend or other distribution of income or capital by us to our shareholders or a payment of principal or interest or other sums due under a debenture or other obligation of us.

We formed CB Pharma for the purpose of entering into a merger, share exchange, asset acquisition, share purchase, recapitalization, reorganization or similar business combination with one or more businesses or entities, which we refer to as a "target business." While our efforts to identify a prospective target business will not necessarily be limited to a particular industry or geographic region of the world, we initially intend to focus our search on target businesses in North America, Europe, South America and Asia operating in the specialty pharma and generic drug industries. This could include our acquiring the rights to a drug approved by the U.S. Food and Drug Administration (the "FDA") or other "branded" pharmaceutical product or a company holding such rights.

Upon formation of CB Pharma, we purchased 1,150,000 insider shares of CB Pharma for $25,000 in a private placement. In December 2014, CB Pharma closed its IPO, including an over-allotment exercise, and a private placement raising net proceeds of $42.9 million, to be held in trust until such time that a business combination is consummated. In conjunction with the IPO, we purchased 265,000 ordinary shares of CB Pharma at $10.00 per share for an aggregate purchase price of $2.7 million pursuant to a private placement. None of the shares we purchased have liquidation rights. Each ordinary share is entitled to a Right, representing one-tenth of a share and a warrant representing one-half of a share at $11.50 per share upon an initial business combination. Our investment in CB Pharma, at December 31, 2014, represents approximately 23% ownership in CB Pharma.

CB Pharma has 18 months from the consummation of its IPO to consummate an initial business combination. If it is unable to consummate an initial business combination within such time period, it will liquidate the trust account and distribute the proceeds held therein to its public shareholders and dissolve. Our investment will not participate in the liquidation.

CB Pharma is managed by our Chief Executive Officer and our Chief Operation Officer.

Our Existing Product Candidates

TSO

TSO, a biologic composed of the microscopic eggs of the porcine parasitic whipworm, is a product candidate for the treatment of immune-mediated diseases. We are currently investigating TSO for the treatment of immune-mediated disorders such as autism spectrum disorder ("ASD"), and supplying TSO to the National Institutes of Health ("NIH") for a study of TSO in ulcerative colitis ("UC").

Background

The approach of using TSO to treat immune-mediated diseases is based on the "hygiene hypothesis," which postulates that multiple childhood exposures to parasites and pathogens protect an individual from allergic and autoimmune disease later in life. In line with these hypotheses, epidemiologic evidence, case control observations, animal studies and clinical studies all suggest that exposure to helminth parasites, which followed the whole of human evolution since its early beginnings, may afford protection from or even treat autoimmune disorders. Co-infection with helminth is known to attenuate immune-mediated diseases in animal models as helminthic colonization can result in increased production of immune-modulatory molecules such as IL-10, transforming growth factor (TGF)-ß, and regulatory T-cells. The use of TSO as a human therapeutic originates from the work of Dr. Joel V. Weinstock, currently the Chief of the Division of Gastroenterology/Hepatology at Tufts New England Medical Center in Boston. Dr. Weinstock's research has centered on the evolutionary role of parasitic helminth infections in the prevention of inflammatory diseases. TSO was chosen as an appropriate helminth for therapeutic application due to its ability to colonize in humans briefly without invading or infecting the host. Although not a human parasite, *T. suis* resembles the human whipworm T. Trichuris and is believed to colonize in a human host for several weeks before being eliminated from the body without the need for antihelminthic therapy. In its natural host, mature *T. suis* produce ova that exit the porcine host with the stool. The ova are not infective until incubating in the soil for several weeks, thereby preventing direct host-to-host transmission. We believe, based upon our significant amount of human experience using TSO and review of the literature, that no human diseases have been associated with exposure to TSO.

Autism Spectrum Disorder

ASD is a severe neurodevelopment disorder of early childhood onset characterized by pervasive deficits in social interaction, communication, unusual preoccupations or interests, and repetitive behaviors. ASD is a serious disability with substantial impact on day-to-day functioning of patients and their families. The most recent Center for Disease Control ("CDC") estimate (March 2014) puts autism prevalence in the United States as one in 68 children. Although ASD is characterized by the core symptoms noted above, many patients will present with difficult behaviors such as hyperactivity, impulsivity, aggression toward people and the environment and self-injury, which may be a form of protest when they experience a deviation from expectations. ASD is considered a developmental or childhood disorder, but only a minority of ASD patients can become independent as adults. The remaining patients require supervision or institutionalized care, making ASD a costly public health problem.

ASD is a complex heterogeneous disorder and different theories regarding its cause have been researched but conclusive evidence regarding what causes ASD remains elusive. Better awareness of the disease, and therefore more frequent diagnoses, cannot alone explain the dramatic increase in disease incidence. ASD has not been linked to a specific gene(s) of major effect. Various environmental factors, such as childhood immunizations, have been thoroughly researched and found not to be the cause. Another possibility is gene-environment mismatch with ASD as the final behavioral manifestation of the effect of multiple etiological pathways, or an array of possible genetic vulnerabilities and gene-environment interactions, on neurodevelopment. In the absence of a gene of major effect, a current consensus view postulates genes of minor effect conferring susceptibility to an environmental cause. It has been documented for some time that there is an association between ASD and immune dysfunction, as a variety of immune system abnormalities have been reported in patients with ASD. Although the neurobiological basis for ASD is not well understood, numerous threads of evidence suggest that immune abnormalities play a role in the pathogenesis of at least a portion of ASD patients. Therefore, a genetic predisposition to immune dysregulation may cause vulnerability to a pathogenesis of ASD via the hygiene hypothesis.

There are no medications that can cure ASD or even treat its main symptoms. There are, however, medications that can help some people with related symptoms. For example, medication might help manage high energy levels, inability to focus, depression, or seizures. Also, the FDA approved the use of risperidone (Risperdal®) and aripripazole (antipsychotic drugs) to treat at certain ages children with ASD who have severe tantrums, aggression, and cause self-injury. Generic forms of Risperdal® are already on the market. While these products may improve the quality of life in some ASD patients with behavior problems and for their families and caregivers, they are associated with a high incidence of undesirable side effects such as weight gain, sedation, fatigue, increased saliva and drooling, Parkinsonism, dystonia and tachycardia.

Our Clinical Trial Program

On-going

In December 2013, we met with the FDA in a "Type B" pre-IND teleconference concerning the clinical and regulatory program for advancing TSO through the clinical trial process and used the feedback from this meeting in the design and implementation of the Phase 2 ASD study. We then launched a Phase 2 study of TSO in ASD patents with immune dysregulation (the "Phase 2 ASD Study") in May 2014. This is a multi-center, randomized, double-blind, placebo-controlled, cross-over study in approximately 20 pediatric ASD patients in the United States. In order to maximize efficacy signal detection, the protocol is designed to enrich with ASD patients with likely immune dysregulation. The study is designed to assess safety and tolerability in the pediatric ASD patients in the age range of five to 17. Subjects will be randomized to receive either TSO or placebo once every two weeks, for 16 weeks, followed with a four-week washout and the opposite treatment for 16 weeks. The primary efficacy endpoint for the study is Aberrant Behavior Checklist – Irritability subscale (ABC-I), which measures TSO's impact on irritability associated with ASD. The ABC consists of 58 items divided into five subscales that rate a child's behaviors, and in the context of this study, is provided by a parent. Each item is rated on a scale from 0-3, with 0 meaning "not at all a problem" and 3 being "the problem is severe in degree." In the pre-IND meeting we conducted with the FDA on December 16, 2013 (the "PreIND Meeting"), the FDA generally agreed with us that the use of ABC-I as an initial primary endpoint, along with other models and scales for investigative secondary endpoints, was appropriate. In addition, one key investigative secondary endpoint is Children's Yale-Brown Obsessive Compulsive Scale Modified for Pervasive Developmental Disorders (CYBOCS-PDD), which measures TSO's impact on certain core symptoms of ASD. Both ABC-I and CYBOCS-PDD are considered validated outcome measures in ASD studies.

Completed

In February 2012, we announced positive results from our Phase 1 clinical trial of TSO in 36 patients with Crohn's disease ("CD"). The trial was a sequential dose-escalation, double-blind, placebo-controlled study to examine safety and tolerability. TSO was shown to be safe and well tolerated, with no serious treatment-related adverse events reported.

In August 2012, we initiated in the United States a Phase 2 randomized, double-blind, placebo-controlled clinical trial of TSO, known as TRUST-I, designed to evaluate the safety and efficacy of TSO in CD. The study enrolled 250 patients with moderate-to-severe CD to receive either 7500 TSO or placebo once every two weeks for 12 weeks. Although we reported that the study did not meet its primary endpoint demonstrating efficacy in CD, there was a non-significant improved response rate of approximately 14% versus placebo. TSO was safe and well tolerated, and adverse events were balanced between the TSO and the placebo groups. The most common adverse event reported was abdominal pain and occurred in 11% of both TSO and placebo patients.

In November 2013, we were informed by Dr. Falk Pharma GmbH ("Falk"), our European development partner, that an independent data monitoring committee ("IDMC") had conducted a second interim analysis of data from approximately 240 patients who completed 12 weeks of treatment in Falk's Phase 2 clinical trial in Europe evaluating TSO in CD. The IDMC recommended that the trial be stopped due to lack of efficacy and noted no safety concerns. Falk advised us that it was adopting the IDMC's recommendations and discontinuing the study. The Falk trial, known as the TRUST-II study, was a double-blind, randomized, placebo-controlled, multi-center Phase 2 study to evaluate the efficacy and safety of three different dosages of oral TSO in patients with active CD.

To date, TSO has been tested in approximately 500 subjects over the last several years. In general, the product has been shown to be safe and well tolerated with no serious treatment related adverse events reported.

Third Party Clinical Trials

On-going

There are a number of on-going investigator-initiated studies using TSO to investigate its safety and effectiveness to treat other diseases and conditions.

The NIH is conducting a study using TSO to treat ulcerative colitis. It is conducting a 120-subject randomized, double-blind, study comparing the change in clinical symptoms of ulcerative colitis (using the ulcerative colitis disease activity index) following 12 weeks of treatment of either placebo or TSO (7500 ova). In addition, we are aware of a multiple sclerosis study and a rheumatoid arthritis study ongoing in Germany.

In April 2014, an investigator-initiated study evaluating TSO in pediatric ASD patients was initiated at the Hadassah-Hebrew University Medical Center in Jerusalem, Israel. Dr. Itai Berger, director of its Neuro-Cognitive Center, is the Principal Investigator of the study. This study is a randomized, double-blind, placebo-controlled, 16-week study designed to enroll 60 patients in the age range of six to 17 years. Patients will be randomized to receive placebo, 2500 TSO or 7500 TSO every other week for 16 weeks. The goal of the pilot study is to test for safety of TSO compared to placebo in pediatric patients with ASD, and evaluate efficacy signals on irritability, repetitive behaviors, global functioning and social cognition.

Completed

In June 2014, we reported topline results from an investigator-initiated study in autism conducted by Dr. Eric Hollander, Clinical Professor of Psychiatry and Behavioral Sciences at Albert Einstein College of Medicine of Yeshiva University and Director of the Autism and Obsessive Compulsive Spectrum Program at Montefiore Medical Center. The study is a double-blind, randomized, placebo-controlled, cross-over study and enrolled 10 high-functioning adult ASD patients who were able to give informed consent to participate in the study and who had a history of allergies and/or a family history of immune-inflammatory illness. Subjects were treated for 12 weeks with either TSO or placebo, followed by a four-week washout phase and then 12 weeks of placebo or TSO. The TSO dosage used in the study was 2500 ova once every two weeks. While none of the measures reached statistical significance, benefits with TSO treatment (over placebo) were observed in several subscales, including the Montefiore-Einstein Rigidity Scale (MERS), ABC-I, RBS-R Sameness, and RBS-R Restricted Behavior. TSO was well tolerated, no patient discontinued due to an adverse event (or due to tolerability issues), and nine of ten patients completed the full 26-week treatment period.

Manufacturing

To date, we have contracted with Ovamed to produce and supply us with all of our requirements of TSO. Ovamed's contractor inoculates young pathogen-free pigs with *T. suis* from a master ova bank and harvests the ova which are incubated to maturity and are processed to remove any viruses and other pathogens. Ova are then processed and extensively tested to assure uniformity. They are then used to repopulate the master ova bank and are processed further by Ovamed into a final formulation of the drug product that is a clear, tasteless and odorless liquid. Ovamed manufacturing is conducted at one facility in Germany, which has received Good Manufacturing Practice, or GMP, certification by the European Medicines Agency, or EMA. Ovamed's manufacturing operations are subject to FDA and EMA standards. See "Government Regulation and Product Approval".

In December 2012, we entered into the Second Amendment amending certain provisions of our exclusive sublicense agreement and our manufacturing and supply agreement and providing for certain additional agreements with Ovamed. Pursuant to the Second Amendment, our exclusive license from Ovamed in the Coronado Territory was amended to include an exclusive license to make and have made product containing TSO for the Coronado Territory (as defined therein) and Ovamed's exclusive supply rights in the Coronado Territory will terminate once we establish an operational manufacturing facility in the United States. The Ovamed License now terminates 15 years from first commercial sale in the United States, subject to earlier termination under certain circumstances.

In exchange, we agreed to pay Ovamed a total of $1,500,000 in three equal installments of $500,000 in each of December 2014, 2015, and 2016. Additionally, in lieu of product supply payments that would have been payable to Ovamed as the exclusive supplier, we will pay Ovamed a manufacturing fee for product manufactured and sold by us. The manufacturing fee (the "Manufacturing Fee") will consist of the greater of (i) a royalty on net sales of product manufactured by us or (ii) a specified amount per unit, known as the Transfer Fee Component. The Manufacturing Fee is subject to certain adjustments and credits and we have a right to reduce the Transfer Fee Component by paying Ovamed an agreed amount within ten business days following FDA approval of a Biologics License Application ("BLA") approving the manufacturing, marketing and commercial sale of product in the United States and an additional amount within ninety days after the end of the first calendar year in which net sales in the Coronado Territory exceed an agreed amount.

Simultaneously with the execution of the Second Amendment, Ovamed assigned to us a five-year property lease in Woburn, MA for space in which we initially planned to establish a TSO manufacturing facility. Ovamed agreed to assist us in establishing the Woburn facility and the Second Amendment contemplates that we and Ovamed would act as second source suppliers to each other at agreed transfer prices pursuant to a Second Source Agreement to be negotiated between us. In 2013, we substantially completed the buildout of the office area in the Woburn facility. However, based upon TRUST-I results in October 2013, we delayed our TSO manufacturing plans and discontinued the buildout of our U.S. manufacturing facility. It will take approximately one year to complete the manufacturing site and will require an incremental investment from us. If completed, the Woburn facility will be required to meet GMP standards and will be subject to FDA and other regulatory authorities' inspections, which could take approximately 12 months from the decision to proceed. On February 27, 2015, Ovamed filed for insolvency in Germany, a process similar to U.S. bankruptcy. At this time, we are unable to assess the likelihood of Ovamed continuing operations or being able to supply TSO. We have sufficient supply to complete our Phase 2 ASD Study and we are assessing our options with respect to future supply.

Strategic Alliances and Commercial Agreements

Sublicense Agreement with Ovamed GmbH

In January 2011, in connection with our acquisition of the assets of Asphelia Pharmaceuticals, Inc. ("Asphelia") relating to TSO, Asphelia assigned the Exclusive Sublicense Agreement, dated December 2005, between Asphelia and Ovamed, as amended (the "Ovamed License"), and the Ovamed License and Manufacturing and Supply Agreement, dated March 2006, between Asphelia and Ovamed, as amended, otherwise known as the Ovamed Supply Agreement, to us and we assumed Asphelia's obligations under these agreements. Under the Ovamed License, we received an exclusive sublicense, with a right to grant additional sublicenses to third parties, under Ovamed's patent rights and know-how to use and sell products encompassing TSO in North America, South America and Japan. Ovamed's patent rights arise, in turn, from an exclusive license granted in 2005 by the University of Iowa Research Foundation, or UIRF, to Ovamed covering inventions and related intellectual property rights that arose as a result of research relating to TSO performed by Dr. Weinstock and his colleagues while employed by the University of Iowa. In November 2011, we entered into an agreement with UIRF and Ovamed primarily amending certain diligence provisions of the UIRF license agreement with Ovamed and obtaining certain rights in the event of an Ovamed breach of this license.

Under the Ovamed License, we are required to make milestone payments to Ovamed totaling up to approximately $5.45 million, of which $3.0 million has been paid, primarily upon the achievement of various regulatory milestones for the first product that incorporates TSO, and additional milestone payments upon the achievement of regulatory milestones relating to subsequent indications. In the event that TSO is commercialized, we are obligated to pay to Ovamed royalties equal to 4% of net sales. Additionally, we are obligated to pay to Ovamed a percentage of certain consideration we receive from sublicensees (ranging from 10% to 20% of such consideration depending on the stage of clinical development at the time of the sublicense), as well as an annual license maintenance fee of $250,000 and reimbursement of patent costs. We are responsible for all clinical development and regulatory activities and costs relating to licensed products in North America, South America and Japan. Either party may also terminate the agreement under certain customary conditions of breach and we have the right to terminate the Ovamed License with 30 days' prior notice.

In January 2011, as part of the purchase price for the Asphelia assets, we paid Ovamed an aggregate of approximately $3.4 million in satisfaction of Asphelia's agreement to pay Ovamed for certain development costs, the annual license maintenance fee and patent reimbursement costs.

Under the Ovamed Supply Agreement, Ovamed agreed to manufacture and supply us with, and we are required to purchase from Ovamed, our clinical and commercial requirements of TSO at pre-determined prices. The Ovamed Supply Agreement automatically renewed for a successive one-year period in March 2014, and will continue to do so each year, unless we give 12 months' prior notice of our election not to renew. The Ovamed Supply Agreement is subject to early termination by either party under certain customary conditions of breach and by us in the event of specified failures to supply or regulatory or safety failures.

We are considering the impact of Ovamed's bankruptcy filing on these agreements.

Collaboration Agreement with Ovamed and Falk

In December 2011, we entered into a binding Terms of Agreement with Falk and Ovamed under which we agreed to enter into a collaboration agreement relating to the development of TSO for CD. In March 2012, the parties entered into the Collaboration Agreement, under which 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 CD, including the ongoing Falk Phase 2 clinical trial, for use in North America, South America and Japan. In exchange, we granted Falk exclusive rights and licenses to our pre-clinical data and data from clinical trials of TSO in CD for use in Europe.

In addition, we agreed to pay Falk a total of €5 million after receipt of certain preclinical and clinical data, half of which was paid in 2012 and half of which was expected to be paid in 2014, and contingent upon Falk delivering the Final Clinical Study Report, or CSR, and a royalty equal to 1% of net sales of TSO in North America, South America and Japan. As of December 31, 2014, we have yet to receive delivery of the CSR.

Under the Collaboration Agreement, a steering committee (the "Steering Committee") composed of our representatives and representatives of Falk and Ovamed will oversee the TSO development program for CD, 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 CD in the United States and Europe and will share in certain pre-clinical development costs. Due to TRUST-I results in mid-October 2013, the Steering Committee agreed to postpone pre-clinical development activities and such activity has not resumed.

The Collaboration Agreement may be terminated by either Falk or us under certain conditions including if the other party fails to cure a material breach under the agreement, subject to prior notice and the opportunity to cure, if the other party is subject to bankruptcy proceedings or if the terminating party terminates all development of TSO

Research Agreement with FU Berlin

On February 22, 2013, we and Freie Universität Berlin, or FU Berlin, entered into a Research Agreement to, among other things, identify and evaluate secretory proteins from *Trichuris suis,* which we refer to as the Project. The duration of the Project is expected to be four years, during which we will pay FU Berlin a total maximum amount of approximately €648,000, or approximately $788,000 in research fees and FU Berlin will periodically produce written progress reports on the Project. The Research Agreement terminates on the later of the date that the last payment or report is due, subject to early termination by either party upon three months' written notice for cause or without cause. If we terminate the Research Agreement, we must pay FU Berlin a termination fee composed primarily of unpaid research fees due on the first payment date after which termination occurred (subject to adjustment), except where termination is due to a breach by FU Berlin which it fails to cure within 60 days' notice or due to FU Berlin's bankruptcy.

On February 22, 2013, we and FU Berlin also entered into a Joint Ownership and Exclusive License Agreement, or JOELA, pursuant to which we agreed to jointly own all intellectual property arising from the Project, which we refer to as the Joint Intellectual Property. FU Berlin also granted us (a) an exclusive worldwide license (including the right to sublicense) to its interest in the Joint Intellectual Property and its know-how related to the Project, which we refer to as the Licensed IP, and (b) the right to commercialize products that, without the licenses granted under the JOELA, would infringe the Licensed IP. FU Berlin retains the non-exclusive and non-transferable right to use the Licensed IP for its own internal, academic purposes. Pursuant to the JOELA, we must pay FU Berlin a total maximum amount of approximately €3,830,000, or approximately $4,655,000 in potential milestone payments, based primarily on the achievement of clinical development and regulatory milestones, and royalties on potential net sales of products ranging from 1.0% to 2.5%. The JOELA continues until the last-to-expire patent in any country, subject to early termination by either party without penalty if the other party breaches the JOELA and the breach is not cured within 60 days after receiving notice of the breach or if a party is in bankruptcy. We also have the right to terminate the JOELA after giving FU Berlin 60 days' written notice of a regulatory action that affects the safety, efficacy or marketability of the Licensed Products (as defined in the JOELA) or if we cannot obtain sufficient materials to conduct trials, or upon 180 days' written notice for any reason.

In connection with the Research Agreement and JOELA, we entered into a License and Sublicense Agreement, or LSA, with Ovamed, on February 22, 2013, pursuant to which we licensed our rights to the Joint Intellectual Property and sublicensed our rights to the Licensed IP to Ovamed in all countries outside North America, South America and Japan, which we refer to as the Ovamed Territory. Pursuant to the LSA, Ovamed would pay us a total maximum amount of approximately €1,025,000, or approximately $1,246,000 based primarily on the achievement of regulatory milestones, and royalties on potential net sales of products ranging from 1.0% to 2.5%, subject to adjustment, in each case equal to the comparable payments due under the JOELA. The LSA continues until the last-to-expire patent in any country in the Ovamed Territory, subject to early termination by either party upon the same terms as in the JOELA.

On February 22, 2013, we, Ovamed and FU Berlin entered into a Letter Agreement to amend a Material Transfer Agreement dated May 14, 2012 by and between Ovamed and FU Berlin. The Letter Agreement provides that Ovamed will retain a 10% interest in FU Berlin's rights to the Joint Intellectual Property in the Ovamed Territory. It also grants Ovamed certain rights if FU Berlin terminates the JOELA due to our breach, including the right to have the JOELA survive and our rights and obligations thereunder assigned to Ovamed.

On March 25, 2014, the Company terminated the Research Agreement effective June 30, 2014. In connection with this termination, the Company incurred a one-time termination fee of $167,000, composed primarily of unpaid research fees, which is included in research and development expenses during the year ended December 31, 2014.

TSO Intellectual Property

Under the Ovamed License, we have exclusive rights to United States Patent Nos. 6,764,838, 7,250,173 and 7,833,537, owned by the University of Iowa and licensed by UIRF to Ovamed. These patents claim, respectively, methods of producing a pharmaceutical composition comprising an helminthic parasite preparation, pharmaceutical compositions suitable for oral administration comprising an isolated and purified *T. suis* helminthic parasite preparation, and methods of treating inflammatory bowel disease, including CD and UC, in an individual by the administration of a helminthic parasite preparation obtained from a group of helminthic parasites. These patents are scheduled to expire in December 2018, except for the '537 patent, which is set to expire approximately nine months later. Under the patent term restoration provisions of the patent laws, we may choose to restore a portion of the term of one of these patents, or any other relevant patents that may be granted prior to marketing approval of TSO, to recover at least a portion of the delays associated with obtaining regulatory approval. We also have exclusive rights through the Ovamed License under a second patent family owned by UIRF, which is directed to methods of using helminthic parasite preparations to treat patients with a Th1 or Th2 related autoimmune disease. Any patents that mature from this second patent family would not expire until at least November 2023.

Under the Collaboration Agreement, we have an exclusive license in North America and Japan to Falk's interest in two patent families: one directed to a process for the preparation of the pharmaceutical product composed of viable eggs of parasitic helminths and another directed to a method of determining biological activity of embryonated *Trichuris* eggs. Applications for patents are pending in the United States, Canada and Japan for both patent families.

Our success for preserving market exclusivity for our product candidates relies on our ability to obtain and maintain a regulatory period of data exclusivity over an approved biologic, currently 12 years from the date of marketing approval, and to preserve effective patent coverage. Once any regulatory period of data exclusivity expires, depending on the status of our patent coverage, we may not be able to prevent others from marketing and selling products that are biosimilar to or interchangeable with our product candidates. We are also dependent upon the diligence of third parties, which control the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

In addition to any regulatory exclusivity we may be able to obtain, we also seek to protect additional intellectual property rights such as trade secrets and know-how, including commercial manufacturing processes and proprietary business practices.

On February 27, 2015, Ovamed filed for insolvency in Germany, a process similar to U.S. bankruptcy. At December 31, 2014, we had not paid the UIRF license fee of $250,000 to Ovamed. We are unable to assess the impact of this non-payment on the license agreement between Ovamed and UIRF.

TSO Competition

In the area of ASD therapies, we are aware of the several products in clinical stage development, including:

- CM-AT, an enzyme therapy for the treatment of ASD, has been granted the Fast Track status by the FDA and has completed a Phase 3 clinical study. In December 2011, Curemark LLC announced that CM- AT met both the primary and secondary endpoints in a Phase 3 double blind randomized placebo controlled multicenter clinical trial. Curemark announced that it began the rolling submission of a New Drug Application ("NDA") for CM-AT in November 2013.

- Latuda (generic name lurasidone), currently marketed by Sunovion Pharmaceuticals Inc. for bipolar depression, is an atypical antipsychotic and is in Phase 3 clinical trials for treating irritability associated with ASD in pediatric ASD patients. Latuda is of the same class of pharmaceuticals as those already approved to treat irritability associated with ASD in pediatric ASD patients. Consequently, we expect that Latuda will offer no greater benefit to patients than the currently marketed pharmaceuticals of the same class which, because of their inability to obtain a durable efficacious response and significant side effects, have extremely limited market penetration.

- RO5028442, a product candidate of F. Hoffmann-La Roche AG, is in a Phase I clinical study of adult male high-functioning autism patients.

If TSO is approved for the treatment of CD, we expect to compete directly with Janssen Biotech Inc.'s (a subsidiary of Johnson & Johnson) Remicade (infliximab), UCB S.A.'s Cimzia (certolizumab pegol) and Abbott Laboratories' Humira (adalimumab), each of which is currently approved for the treatment of various diseases, including irritable bowel disease, UC and CD, and several other products. TSO, if developed and approved for the treatment of multiple sclerosis ("MS"), would compete with Biogen Idec's Avonex (interferon beta-1a), Bayer Healthcare Pharmaceuticals' Betaseron (interferon beta-1b), Teva Pharmaceuticals Industries, Ltd.'s Copaxone (Glatiramer Acetate) and Novartis AG's Gilenya (fingolimod) and several other products. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

CNDO-109

CNDO-109 is a lysate (disrupted CTV-1 cells, cell membrane fragments, cell proteins and other cellular components) that activates donor Natural Killer ("NK") cells. CTV-1 is a leukemic cell line re-classified as a T-cell acute lymphocytic leukemia, or ALL. We acquired exclusive worldwide rights to develop and commercialize CNDO-109 activated NK cells for the treatment of cancer from UCLB. We are sponsoring an ongoing Phase 1/2 study in patients with acute myeloid leukemia ("AML") who are in their first complete remission ("CR1") and who are at a high risk of relapsing. This study has completed enrollment and is expected to remain open to follow the status of patients until mid-2015.

Background

Standard therapy for patients with advanced cancer include chemotherapy, or therapies that are toxic to the cells, that suppress the immune system and carry significant risks of life-threatening infections and other toxicities in the absence of hope for cure. Despite effective cancer therapies that induce clinical responses, including complete remissions, minimal residual disease, or MRD, a term referring to disease that is undetectable by conventional morphologic methods, often remains and serves as a source of cancer recurrence. For years, scientists have studied ways to enhance the patient's immune system to target cancer cells, maintain remission and possibly even eradicate all cancer cells in the body, including MRD. Researchers believe that a cure for cancer might be possible if immunotherapy is successfully applied to the treatment of cancer.

The most common immunotherapy studied to date involves the use of targeted humanized monoclonal antibodies such as rituximab (anti-CD20) or trastuzumab (anti-HER2/neu). These antibodies bind targets that are over-expressed on cancer cells and promote cell death by a number of immune mechanisms, including antibody dependent cell-mediated cytotoxicity, or ADCC. In ADCC, the most common mechanism of tumor killing, the antibody tags the cancer cell and recruits the cells from the patient's immune system to attack the tumor. Immune cells recruited by the antibody to kill the cancer include granulocytes, macrophages and NK cells.

Another common therapy that activates the innate immune system involves the administration of high dose Interleukin-2, or IL-2. Through binding to the IL-2 receptor, IL-2 activates NK cells to attack cancer cells. After high-dose IL-2 therapy, NK cells are activated to search out and kill cancer cells. Unfortunately, the use of IL-2 therapy is limited because of its severe side effects, which include severe life-threatening infusion reactions and induction of autoimmune disease.

The importance of NK cells in the host system's defense against cancer was recognized by Dr. Mark Lowdell at the Royal Free Hospital in London and others when they noted that patients who could mount an immune response to their AML became long-term survivors after chemotherapy. Researchers identified that a key to the successful immune response of the patient's immune systems was the NK cell. Dr. Lowdell determined that activated NK cells were the key to eliminating AML cells and that NK cells require two signals to kill a tumor cell—a priming signal followed by a trigger signal. NK cells that can be activated by certain cancer cells provide both signals resulting in killing the cancer cell. Cancer cells that cannot be killed only trigger one signal and therefore are considered resistant to NK cells. NK cells which have not been primed cannot respond to the trigger. The "priming signal" can be provided by either cytokines, such as high dose IL-2 or IL-15 or by CNDO-109. In contrast to IL-2 or IL-15, NK cells activated by CNDO-109 retain their activated state after freezing and thawing. This allows commercialization of the process since the NK cells can be activated with CNDO-109 and prepared at a central manufacturing facility under GMP conditions and shipped to the clinical center as a frozen patient-specific dose, ready for infusion. The results of the research conducted by Dr. Lowdell and his colleagues were published in the *British Journal of Haematology* in 2002 and *The Journal of Immunology* in 2007 and all inventions and related intellectual property that arose from such research are covered by our license agreement with UCL Business PLC, or UCLB. Dr. Lowdell is a consultant to us.

Although AML is the prototype tumor lysed by CNDO-109 activated NK cells, CNDO-109 activated NK cells are expected to be active against many cancer types. Based on *in vitro* preclinical efficacy studies of CNDO-109 conducted by Dr. Lowdell at the Royal Free Hospital in London using human specimens of breast cancer, prostate and ovarian cancer, we expect CNDO-109 to be active against tumors that have been successfully treated by high dose IL-2 therapy such as renal cell carcinoma and melanoma.

The treatment of patients with CNDO-109 activated NK cells involves several steps. The activated NK cells are infused into the patient after resting NK cells are incubated with CNDO-109 for at least four hours. Preparation of CNDO-109 activated NK cells takes about 24 hours from start to finish. If the source of the NK cells being used is someone other than the patient, "an allogeneic donor," the patient will need some form of immunosuppression to allow the CNDO-109 activated NK cells to persist long enough to eradicate MRD. Preliminary data on a small number of patients from the UK Phase 1 clinical trial demonstrated that CNDO-109 activated NK cells can remain active for weeks.

Oncology Therapeutics Markets

The American Cancer Society estimates that over 1.6 million people in the United States are expected to be diagnosed with cancer in 2012, excluding basal and squamous cell skin cancers and *in situ* carcinomas (other than urinary bladder carcinomas). This is an increase of approximately 33% from the estimated number of new cancer diagnoses in 2000. We believe this rate is unlikely to decrease in the foreseeable future as the causes of cancer are multiple and poorly understood.

Despite continuous advances every year in the field of cancer research, we believe there remains a significant unmet medical need in the treatment of cancer, as the overall five-year survival rate for a cancer patient diagnosed between 2001 and 2007 still averages only 67% according to the American Cancer Society. According to that same source, cancer is the second leading cause of mortality in the United States after heart disease. The American Cancer Society estimates that approximately one in four deaths in the United States is due to cancer.

AML is one of the most deadly and most common types of acute leukemia in adults. According to a 2011/2012 *Decision Resources* report, there are over 43,000 cases worldwide, primarily afflicting elderly and relapsed and refractory populations. Once diagnosed with AML, patients typically receive induction and consolidation chemotherapy, with the majority achieving complete remission. However, about 70–80% of patients who achieve first complete remission will relapse, and the overall five-year survival rate is less than 25%.

One of the main treatments for cancer is chemotherapy. While chemotherapy is the most widely used class of anti-cancer agents, individual chemotherapeutic agents often show limited efficacy because tumors maintain complex machinery to repair the DNA damage to tumor cells caused by chemotherapy. Solutions to this problem include combination chemotherapy, but while combination chemotherapy has been intensively studied, it offers only limited hope for improvement as a result of additive toxicities. The limitations inherent in chemotherapy are mirrored by limitations in other therapeutic modalities for cancer, including radiation therapy, targeted therapies and surgical intervention. Each of these therapies either has high levels of toxicity and/or potentially severe adverse events, which in turn frequently limit the amount of treatment that can be administered to a patient.

As a result, we believe that there is a significant unmet medical need for alternatives to existing chemotherapy drugs that do not have the associated toxicities of traditional chemotherapy drugs.

Completed Clinical Trial

An investigator-initiated Phase 1 clinical trial of CNDO-109 activated haploidentical NK cells was conducted at the Royal Free Hospital in London in eight patients with high risk (i.e. chemo-sensitive relapsed/refractory) AML who were not eligible for a stem cell transplant. The results of this trial were presented at the ASH Annual Meeting in December 2011. Although the primary endpoint of the Phase 1 clinical trial was safety, the results demonstrated that the majority of AML patients experienced a longer complete remission after receiving CNDO-109 activated NK cells than their previous complete remission. This finding is notable since the duration of each successive complete remission is generally shorter than the last.

Our Clinical Program

We submitted an IND for the CNDO-109 activated NK cell product in the United States in February 2012 using data from UCLB's Phase 1 clinical trial in the United Kingdom. We initiated a Phase 1/2 clinical trial in the United States in November 2012 using CNDO-109 to activate NK cells to treat AML patients in CR1 who are deemed at a high risk to relapse. In Phase 1/2 oncology clinical trials, dose limiting toxicity stopping rules are commonly applied. The CNDO-109 Phase 1/2 trial is subject to a set of dose-limiting toxicities, or 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 reported on an interim analysis of study data at the annual meeting of the American Society of Hematology ("ASH") in 2014. At that time, we completed the dose escalation (i.e. Phase 1) stage of the study and nine patients had been treated at three dose levels: 3×10^5, 1×10^6, and 3×10^6 activated NK (aNK) cells/kg. The maximum tested dose or recommended dose for Phase 2 studies in this indication was defined as 3×10^6 aNK cells/kg. There was no infusional toxicity, adverse events attributed to CNDO-109/NK cell therapy. Further, graft-versus-host disease was not observed. As expected, all patients experienced transient myelosuppression (approx. two weeks) and relapse-free survival averaged 6.3 months (range, 3.4-15.8) from the time that they were declared to be in their first complete remission. A single death occurred due to unrelated reasons.

In 2014, we completed dose escalation onto the Phase 1 portion of the clinical trial; study patients are being followed and laboratory studies aimed at assessing various exploratory endpoints are undergoing completion. To date, no DLTs have been observed. With regard to exploratory studies assessing donor chimerism and the persistence of aNK following treatment, we measured persistence of donor activated NK cells was observed from Day +7 post-infusion (chimerism = 1%-84%) to as late as day +56 in 7 of 9 patients studied. Even after loss of circulating donor primed NK cells, several patients tested showed persistence of low levels of activated autologous NK cells, out to Day +56, suggesting that the therapy may induce endogenous NK activation to enhance the patients' innate immunity to AML. We plan to finalize the collection of clinical and exploratory data in early 2015, which will be assessed to determine subsequent developmental directions.

Manufacturing

The manufacturing process for CNDO-109 activated NK cells is currently under development. We have produced a master cell bank and a working cell bank of CTV-1 cells in collaboration with BioReliance Corp ("BioReliance"). Manufacture and testing of CNDO-109 activated NK cells for our ongoing Phase 1/2 clinical trial is being conducted by Progenitor Cell Therapy, LLC ("PCT"). We have entered into master service agreements with both companies as well as a supply agreement with PCT. In February 2013, we entered into a master service agreement with WuXi AppTec ("WuXi"), pursuant to which WuXi will provide product development, manufacturing and testing services related to CNDO-109. We pay for services under the agreement pursuant to statements of work entered into with WuXi from time to time. Through December 31, 2014, we have entered into statements of work with WuXi with $0.7 million remaining. The master service agreements provide the general framework for our relationship with BioReliance, PCT and WuXi, with specific terms to be established in connection with particular projects.

License Agreement with UCLB

In November 2007, we entered into a license agreement with UCLB under which we received an exclusive, worldwide license to develop and commercialize CNDO-109 to activate NK cells for the treatment of cancer and related conditions. Pursuant to a September 2009 amendment, we also received a non-exclusive license, without the right to sublicense, to certain clinical data solely for use in the IND for CNDO-109. Under a May 2012 amendment, additional patent rights and rights to certain additional inventions were added to the license agreement.

In consideration for the license, we will be required to make future milestone payments totaling up to approximately $22 million contingent upon the achievement of various milestones related to regulatory events for the first three indications for which CNDO-109 is developed. In March 2012, we recognized our obligation to pay UCLB a $250,000 milestone related to the filing of an IND for CNDO-109. In the event that CNDO-109 is commercialized, we will be obligated to pay to UCLB royalties ranging from 3% to 5% of net sales of the product or, if commercialized by a sublicensee, a percentage of certain consideration we receive from such sublicensee (ranging from 20% to 30% of such consideration depending on the stage of clinical development at the time of the sublicense). Under the terms of the agreement, we must use diligent and reasonable efforts to develop and commercialize CNDO-109 activated NK cells worldwide and may grant sublicenses to third parties without the prior approval of UCLB. In September 2012, the U.S. Patent and Trade Office (the "PTO") granted the first U.S. patent directed to CNDO-109. Foreign counterparts to this patent claim have been granted in India and Australia. In June 2012, we were notified by the FDA that CNDO-109 was granted orphan drug designation. In February 2014, a second key patent directed to compositions comprising these activated NK cells was granted. We have exclusive worldwide rights to develop and market CNDO-109 under a license agreement with the University College London Business PLC, or UCLB.

The agreement with UCLB terminates upon the expiration of the last licensed patent right, unless the agreement is earlier terminated. Either party may terminate the agreement in the event of material breach by the other party, subject to prior notice and the opportunity to cure, or in the event the other party enters into bankruptcy or is dissolved for any reason other than in connection with a merger or acquisition. UCLB may terminate the license agreement if we, or our affiliates, commence or assist in legal proceedings to challenge the validity or ownership of the patents licensed to us under the agreement, or if we market or sell a competing product without UCLB's prior written consent. In addition, we may terminate the agreement by providing written notice to UCLB at least 30 days' prior to any contemplated termination.

We have entered into consulting agreements with Dr. Mark Lowdell and UCL Consultants Limited (a wholly owned subsidiary of UCLB) that provide for Dr. Lowdell to provide various services to us relating to our CNDO-109 program. In February 2015, Dr. Lowdell notified us of the termination of the consulting agreements as a result of Phase 1/2 clinical trial nearing its completion.

CNDO-109 Intellectual Property

We have exclusive rights to International Patent Application No. PCT/GB2006/000960 and all pending United States and foreign counterpart applications including granted U.S. Patents No. 8,257,970 and 8,637,308 and the corresponding national phase applications granted in Australia and India and filed in Canada, Europe and Japan, directed to the stimulation of NK cells and related CNDO-109 compositions and methods including methods for the treatment of cancer and other conditions. This patent family has been in-licensed on an exclusive basis from UCLB. This CNDO-109 patent has an expiration date of January 2029 in the absence of any patent term extension.

By way of an amendment to the license agreement with UCLB, we also have exclusive rights to International Application No. PCT/GB2010/051135 and all pending United States and foreign counterpart applications including pending United States Patent Application Serial No. 12/833,694 and the corresponding national phase applications filed in Europe, Brazil, China, Israel, Singapore and South Africa, directed to the preservation of activated NK cells and related compositions and methods. The CNDO-109 patents that may issue from the former patent family would expire in July 2030 in the absence of any patent term extension. The amendment includes rights to certain additional confidential technologies as well.

CNDO-109 Competition

Each cancer indication for which we may develop products has a number of established therapies with which our candidates will compete. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new cancer development programs, including both therapies with traditional, as well as novel, mechanisms of action. Some of the anticipated competitor treatments for AML include Genzyme Corporation's Clolar (clofarabine), currently approved as a treatment for Acute Lymphoblastic Leukemia (ALL), Eisai Corporation's Dacogen (decitabine), currently approved as a treatment for Myelodysplastic Syndromes, or MDS, Celgene Corporation's Vidaza (azacitidine), currently approved as treatments for MDS, and Sunesis Pharmaceuticals, Inc.'s vosaroxin and Ambit Bioscience, Inc.'s quizartinib, which are currently being developed as a treatment for AML, any or all of which could change the treatment paradigm of acute leukemia. Each of these compounds is further along in clinical development than is the CDNO–109 activated NK cell product.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisers, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisers and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Competition

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. 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 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.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing.

United States Pharmaceutical Product Development Process

In the United States, the FDA regulates pharmaceutical (drug and biologic) products under the Federal Food, Drug and Cosmetic Act, and implementing regulations. Pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product-development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a pharmaceutical product may be marketed in the United States generally includes the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to good laboratory practices ("GLPs") or other applicable regulations;
- Submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin in the United States;
- Performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or GCPs, to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;
- Submission to the FDA of an NDA or BLA for a new pharmaceutical product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with the FDA's cGMP, to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength, quality and purity;
- Potential FDA audit of the preclinical and clinical trial sites that generated the data in support of the NDA/ BLA; and
- FDA review and approval of the NDA/BLA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Products for somatic cell therapy are derived from a variety of biologic sources, including directly harvested autologous, allogeneic, or cultured cell lines. Product safety requires that these sources be well characterized, uniform, and not contaminated with hazardous adventitious agents. Also, cells directly from humans pose additional product safety issues. Because of the complex nature of these products, a controlled, reproducible manufacturing process and facility are required and relied on to produce a uniform product. The degree of reliance on a controlled process varies depending on the nature of the product. Because complete chemical characterization of a biologic product is not feasible for quality control, the testing of the biologic potency receives particular attention and is costly.

Before testing any compounds with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be certain that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

Clinical trials involve the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by the sponsor. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA if conducted under a U.S. IND. Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an Investigator Review Board, or IRB, or ethics committee if conducted outside of the United States, at or servicing each institution at which the clinical trial will be conducted. An IRB or ethics committee is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB or ethics committee also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. We intend to use third-party clinical research organizations ("CROs") to administer and 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 and to play a significant role in the subsequent collection and analysis of data from these trials. The failure by any of such third parties to meet expected timelines, adhere to our protocols or meet regulatory standards could adversely impact the subject product development program. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The pharmaceutical product is usually introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer treatments, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2. The pharmaceutical product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA/BLA or foreign authorities for approval of marketing applications.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be requested by the FDA as a condition of approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or, if used, its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB or ethics committee can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's or ethics committee's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

United States Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other relevant information are submitted to the FDA as part of an NDA/BLA requesting approval to market the product.

The NDA/BLA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA/BLA does not satisfy the criteria for approval. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. Drug manufacturers and their subcontractors are required to register their establishments with the FDA, and are subject to periodic unannounced inspections by the FDA for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our suppliers will be able to comply with the cGMP and other FDA regulatory requirements.

Post-Approval Requirements

Any pharmaceutical products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties.

The FDA also may require Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

Orphan Drugs

Under the Orphan Drug Act, special incentives exist for sponsors to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the United States. Requests for orphan drug designation must be submitted before the submission of an NDA or BLA. In June 2012, we were notified by the FDA that CNDO-109 was granted orphan drug designation and in September 2012, the PTO issued the first U.S. patent covering CNDO-109. If CNDO-109 is commercialized, we will be obligated to pay UCLB annual royalties based upon the net sales of product or if we sublicense CNDO-109, a portion of sub-licensing revenue we receive, if any.

If a product that has an orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity for that use. This means that, subsequent to approval, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. The FDA may approve a subsequent application from another person if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. If the FDA approves someone else's application for the same drug that has orphan exclusivity, but for a different use, the competing drug could be prescribed by physicians outside its FDA approval for the orphan use, notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another person from receiving approval for the same or a similar drug for the same or other uses.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs and BLAs or supplements to NDAs and BLAs must contain data to assess the safety and effectiveness of the treatment for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the treatment is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any product for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides BLA holders a six-month extension of any exclusivity—patent or non-patent—for a product if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within a specific time frame.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our products to enable us realize an appropriate return on our investment in research and product development. We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the health care reform legislation enacted in 2010, known as the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework could have a material adverse effect on our business.

International Regulation

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical trials and commercial sales and distribution of any product candidates. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

Employees

As of December 31, 2014, we had 16 full-time employees.

Executive Officers

The following table sets forth certain information about our executive officers as of December 31, 2014.

Name	Age	Position
Lindsay A. Rosenwald, M.D.	59	Chairman of the Board of Directors, President and Chief Executive Officer
Lucy Lu, M.D.	39	Executive Vice President and Chief Financial Officer
George Avgerinos, Ph.D.	62	Senior Vice President, Biologics Operations
Michael S. Weiss	48	Executive Vice Chairman Strategic Development

Lindsay A. Rosenwald, M.D. has served as a member of our board of directors since October 2009 and our Chairman, President and Chief Executive Officer since December 2013. Since November 2008, Dr. Rosenwald has served as Co-Portfolio Manager and Partner of Opus Point Partners Management, LLC ("Opus Point"), an asset management firm in the life sciences industry, which he joined in 2009. Prior to that, from 1991 to 2008, he served as the Chairman of Paramount BioCapital, Inc. Over the last 23 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and has been involved in the founding and recapitalization of numerous public and private biotechnology and life sciences companies. Dr. Rosenwald received his B.S. in finance from Pennsylvania State University and his M.D. from Temple University School of Medicine.

Lucy Lu, M.D. has served as our Executive Vice President and Chief Financial Officer since February 22, 2012. Dr. Lu has over 10 years of experience in the healthcare industry. From February 2007 through January 2012, Dr. Lu was a senior biotechnology equity analyst with Citigroup Investment Research. From 2004 until joining Citigroup, she was with First Albany Capital, serving as Vice President from April 2004 until becoming a Principal of the firm in February 2006. Dr. Lu holds an M.D. degree from the New York University School of Medicine and an M.B.A. from the Leonard N. Stern School of Business at New York University. Dr. Lu obtained a B.A. from the University of Tennessee's College of Arts and Science.

George Avgerinos, Ph.D. has served as our Senior Vice President, Biologics Operations since June 2013. Dr. Avgerinos joined us from AbbVie Inc., where he was Vice President, HUMIRA® Manufacturing Sciences and External Partnerships. In his 22-year career at AbbVie, formerly Abbott Laboratories, formerly BASF Bioresearch Corporation (BASF), Dr. Avgerinos was responsible for many aspects of biologics development and operations. These included the HUMIRA® operations franchise, global biologics process and manufacturing sciences, biologics CMC, manufacturing operations, and third-party manufacturing. During his tenure, Dr. Avgerinos led and participated in the development of numerous clinical candidates which included the launch of HUMIRA®. He supported expansion of the supply chain to over $9 billion in annual global sales. Dr. Avgerinos' efforts on HUMIRA® have been recognized with numerous awards, including the prestigious Abbott's Chairman's award in 2011. Dr. Avgerinos received a B.S. in Biophysics from the University of Connecticut and a Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology.

Michael S. Weiss has served as our Executive Vice Chair Strategic Development since February 2014. Since December 2011, Mr. Weiss has served as Executive Chairman, and Interim President and CEO of TGTX. Mr. Weiss is a co-founder of, and has been a managing partner and principal of Opus Point since 2008. Mr. Weiss earned his J.D. from Columbia Law School and his B.S. in Finance from The University at Albany. He began his professional career as a lawyer with Cravath, Swaine & Moore. In 1999, Mr. Weiss founded Access Oncology which was later acquired by Keryx Biopharmaceuticals (NASDAQ: KERX) in 2004. Following the merger, Mr. Weiss remained as CEO of Keryx and grew the company to close to a $1B market capitalization company at its peak. While at Keryx, he raised over $150MM in equity capital through public and private offerings, executed a $100MM+ strategic alliance, negotiated multiple Special Protocol Assessments ("SPA") agreements with the FDA and managed multiple large clinical trials.

Available Information

We file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy and information statements and amendments to reports filed or furnished pursuant to Sections 13(a), 14 and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The public may obtain these filings at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding our Company and other companies that file materials with the SEC electronically. Copies of our reports on Form 10-K, Forms 10-Q and Forms 8-K may be obtained, free of charge, electronically through our website at www.coronadobiosciences.com.

Item 1A. Risk Factors

Our business operations face a number of risks. These risks should be read and considered with other information provided in this Annual Report on Form 10-K.

Risks Related to our Growth Strategy

In-licensing, acquiring or investing in pharmaceutical and biotechnology products, technologies and/or companies may negatively impact our operating results.

Our business strategy contemplates growth and product diversification. We continue to identify, evaluate and in-license, acquire and invest in pharmaceutical and biotechnology products, technologies and/or companies through our multiple subsidiaries. However, we cannot assure you that any such transaction will be successful or that we will realize the anticipated benefits of any such transaction.

In addition, we have not determined whether or how to consolidate the operations of any business we may acquire. As such, it may be difficult to consolidate the operations of businesses we may acquire with our existing operations or make other changes with respect to acquired businesses, which could in turn result in additional costs or other expenses. Our results of operations also may be adversely affected by expenses we incur in making acquisitions. For example, our results of operations may be impacted by expenses, including legal and accounting fees, incurred in connection with potential transactions, amortization of acquisition-related intangible assets with definite lives, charges associated with the acquisition of incomplete technologies such as in-process research and development and by additional depreciation expense attributable to acquired assets. Any of the businesses or other assets we acquire may also have liabilities or adverse operating issues, including some that we fail to discover before completing the acquisition, and our indemnity for such liabilities may be limited.

Our collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate substantial reliance upon strategic collaborations for marketing and the commercialization of our product candidates and we may rely even more on strategic collaborations for research and development ("R&D") of our other product candidates. We may sell our product offerings through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited.

If we determine to enter into R&D collaborations during the early phases of drug development, our success will in part depend on the performance of our research collaborators. We will not directly control the amount or timing of resources devoted by our research collaborators to activities related to our drug candidates. Our research collaborators may not commit sufficient resources to our programs. If any research collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our drug candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop.

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- coordination of our marketing and R&D programs with the marketing and R&D priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

Many of our potential income generating investments are in companies that have limited commercialized revenue-generating products, which may negatively impact our investment returns.

We have made and will likely continue to make investments in companies that, at the time of investment, have limited or no commercialized revenue-generating products. The ultimate success of our investments in these companies will depend on the ability of such companies to innovate, develop and commercialize products in increasingly competitive and highly regulated markets. If the companies in which we invest do not successfully commercialize any products, the value of our investments will be negatively affected.

We may not be able to manage our anticipated growth, which may in turn adversely impact our business.

We will need to continue to expend funds on improving our infrastructure to address our anticipated growth. Acquisitions, even through our multiple subsidiaries, could place a strain on management, and administrative, operational and financial systems. In addition, we may need to hire, train and manage more employees, focusing on their integration with our Company and corporate culture. Integration and management issues associated with increased acquisitions may require a disproportionate amount of our management's time and attention and distract our management from running our business.

As we continue to execute our growth strategy, we may be subject to further government regulation which would adversely affect our operations.

If we engage in business combinations and other transactions that result in our Company holding passive investment interests in a number of entities, we may become subject to regulation under the Investment Company Act of 1940, as amended (the "Investment Company Act"). If we do become subject to the Investment Company Act, we would be required to register as an investment company and could be expected to incur significant registration and compliance costs in the future.

We may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop our products and businesses.

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, and on our ability to attract additional personnel as we seek to implement our growth strategy and develop our existing products. During our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, as we implement our growth strategy and the demands on our key employees expand, we will continue to be required to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions could adversely affect our business.

We currently depend heavily upon the efforts and abilities of our management team. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results. In addition, we have not obtained, do not own, nor are we the beneficiary of key-person life insurance for all of our key personnel. We only maintain a limited amount of directors and officers liability insurance coverage to protect all of our directors and executive officers taken together. There can be no assurance that this coverage will be sufficient to cover the costs of the events that may lead to its invocation, in which case, there could be a substantial impact on our ability to continue operations, should such an unforeseen event occur.

Risks Related to Our Business and Industry

We are an early-stage company, with limited operating history upon which stockholders can base an investment decision.

We remain an early-stage biopharmaceutical company. To date, we have engaged primarily in R&D activities and have not generated any revenues from product sales. We have incurred significant net losses since our inception. As of December 31, 2014, we had an accumulated deficit of approximately $141.7 million. We have not demonstrated our ability to perform the functions necessary for the successful commercialization of any of our products. The successful commercialization of any of our current 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 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, and, most recently, to executing our growth strategy. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to commercialize our current product candidates, develop potential product candidates and the advisability of investing in our securities.

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

Our existing 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.

On October 14, 2013, we announced that our TRUST-I study did not meet its primary endpoint of improving response, defined as a 100-point decrease in the CDAI, nor the key secondary endpoint of remission, defined as achieving CDAI $\leq$ 150 points. In the overall patient population, response rate of patients on TSO did not separate from that of placebo. The randomization was stratified by disease activity as measured by CDAI. In the corresponding pre-defined subset analysis, TSO showed a non-significant improved response in patients with CDAI>290. The lack of overall response was driven by higher-than-expected placebo response rate in patients with CDAI<290. While we are continuing to analyze the trial data, the results of this trial negatively impact the potential for successful development of TSO.

In November 2013, Falk informed us that an IDMC had conducted a second interim analysis of data from approximately 240 patients who had completed 12 weeks of treatment in Falk's Phase 2 clinical trial in Europe evaluating TSO in CD. The committee recommended that the trial be stopped due to lack of efficacy and noted no safety concerns. Falk adopted the committee's recommendations and discontinued the study. The Falk trial, also known as the TRUST-II study, is a double-blind, randomized, placebo-controlled, multi-center Phase 2 study to evaluate the efficacy and safety of three different dosages of oral TSO in patients with active CD.

In December 2013, we met with the FDA in a "Type B" pre-IND teleconference concerning the clinical and regulatory program for advancing TSO through the clinical trial process and used the feedback from this meeting in the design and implementation of the Phase 2 ASD study. We then launched a Phase 2 study of TSO in ASD patents with immune dysregulation (the "Phase 2 ASD Study") in May 2014. We have not yet determined the development path, if any, for TSO and cannot give any assurances as to the outcome of the Phase 2 ASD study, the future development of TSO, the indications for which TSO could be a treatment, or the costs and timelines for any development plans. 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 your investment in our Company.

Because we in-licensed our existing 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 existing 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, 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. As of December 31, 2014, we owed approximately $250,000 pursuant to such license. If such amounts are not paid, UIRF may declare a breach of the license agreement, which would adversely affect our ability to commercialize TSO.

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. On February 27, 2015, Ovamed, our only supplier and manufacturer of TSO, filed for insolvency in Germany, a process similar to U.S. bankruptcy. At this time, we are unable to assess the likelihood of Ovamed continuing operations or being able to supply TSO.

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 existing 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 an NDA or BLA to the FDA and even fewer are approved for commercialization.

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

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

The FDA and other regulatory agencies 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 that of the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may fail to approve our manufacturing processes or facilities or those of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale. For example, in Phase 1/2 oncology trials, dose limiting toxicity, or DLT, stopping rules are commonly applied. Our CNDO-109 Phase 1/2 trial is subject to a set of DLTs that could suspend or stop dose escalation by predetermined criteria, including allergic reactions, prolonged aplasia or other organ toxicities of a serious nature.

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

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

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

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining IRB or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues. Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

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

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

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

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

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

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

We have abandoned our plans to produce clinical supplies and commercial supplies of TSO in the Woburn facility and our dependence on third-party suppliers for TSO could adversely impact our business.

Based upon TRUST-I results in October 2013, we abandoned our plans to manufacture TSO and discontinued the buildout of our U.S. manufacturing facility in Woburn, MA. As such, we continue to rely exclusively on Ovamed to supply us with our requirements of TSO. On February 27, 2015, Ovamed filed for insolvency in Germany, a process similar to U.S. bankruptcy. As a result, we are unable to assess the likelihood of Ovamed continuing operations or supplying TSO. 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 may adversely affect clinical development and potential commercialization of the product. In the event that the FDA or other agencies determine that Ovamed or 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. Furthermore, if Ovamed or any other contract manufacturer who supply Ovamed cannot successfully manufacture material that conforms to our specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for TSO. Ovamed and our third-party suppliers are and will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of Ovamed's facilities or operations or of our third-party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

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

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

We currently rely completely on WuXi, PCT and BioReliance to manufacture our preclinical and clinical pharmaceutical supplies of CNDO-109 and expect to continue to rely on them and other contractors to produce commercial supplies of CNDO-109, and our dependence on third-party suppliers could adversely impact our business.

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

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

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

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

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

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

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

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

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

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

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

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

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- acceptance of the product by the target population;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

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

We may 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.

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 and 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 business, financial condition and results of operations may be subject to risks arising from the international scope of our product development.

TSO is manufactured outside the United States and, in light of our growth strategy, we may continue to do business in or acquire products from new countries, including emerging markets. As a result, we may be subject to risks inherent in conducting business abroad, including, among other things:

- difficulties in coordinating and managing foreign activities, including ensuring that foreign activities comply with foreign laws as well as U.S. laws applicable to U.S. companies with foreign operations, such as export laws and the U.S. Foreign Corrupt Practices Act, or FCPA;
- price and currency exchange controls;
- credit market uncertainty;
- political and economic instability;
- compliance with multiple regulatory regimes;
- less established legal and regulatory regimes in certain jurisdictions, including as relates to enforcement of anti-bribery and anti-corruption laws and the reliability of the judicial systems;
- differing degrees of protection for intellectual property;
- unexpected changes in foreign regulatory requirements, including quality standards and other certification requirements;
- new export license requirements;

- adverse changes in tariff and trade protection measures;
- differing labor regulations;
- restrictive governmental actions;
- difficulties with licensees, contract counterparties, or other commercial partners; and
- differing local product preferences and product requirements.

Any of these factors, or any other international factors, could have a material adverse impact on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

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

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

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

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

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

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

In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, and includes a number of significant changes to U.S. 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 PTO implemented the America Invents Act on March 16, 2013, and it remains to be seen how the judicial system and the PTO will interpret and enforce these new laws. Accordingly, it is not clear what impact, if any, 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 on our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

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

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

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

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

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if we obtain regulatory approval of a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. We also may be subject to state laws and registration requirements covering the distribution of our products. Later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on such products, manufacturers or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements to approved applications that we submit;
- refusal to permit the import or export of our products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

If we, or our suppliers, third-party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our collaborators may lose marketing approval for our products when and if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties.

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

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

We are an early-stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We continue to generate operating losses in all periods including losses of approximately $27.6 million, $37.2 million and $20.4 million for the years ended December 31, 2012, 2013 and 2014, respectively. At December 31, 2014, we had an accumulated deficit of approximately $141.7 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates and realize our growth strategy. 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 and growth strategy, we are unable to predict the extent of any future losses, whether we will ever generate significant or any revenues or if we will ever achieve or sustain profitability.

We repaid our existing $15.0 million term loan agreement with Hercules in February 2014 and replaced it with a promissory note in favor of Israel Discount Bank of New York ("IDB"). At December 31, 2014, the amount of debt outstanding under the promissory note in favor of IDB was $14.0 million. The loan is collateralized by a security interest, a general lien upon, and right of set off against our money market account of $15.0 million. If we default on our obligations, IDB may declare the loan immediately payable together with accrued interest and exercise its right to set-off. 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 promissory note with IDB may limit our ability to finance future operations or satisfy capital needs or to engage in, expand or pursue our business activities. It may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

We may need substantial additional funding and may be unable to raise capital when needed, which may force us to delay, curtail or eliminate one or more of our R&D programs and commercialization efforts and potentially change our growth strategy.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2012, 2013 and 2014 we incurred R&D expenses of approximately $17.5 million, $25.7 million and $10.2 million, respectively. Since our inception in 2006, we incurred R&D expenses of approximately $77.9 million. We expect to continue to spend significant amounts on product development, including conducting clinical trials for our current product candidates as well as potentially new product candidates, and on our growth strategy. We believe that our cash as of December 31, 2014, will enable us to continue to fund operations in the normal course of business for at least the next 12 months. In addition, in February 2015, we raised $10 million in a private offering of a promissory note to NSC BIOTECH VENTURE FUND I LLC. However, until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance potential, longer-term cash needs. Our ability to obtain additional funding when needed, changes to our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our planned R&D activities, expenditures and growth strategy, increased expenses or other events may affect our need for additional capital in the future and require us to seek additional funding sooner than anticipated. In addition, if we are unable to raise additional capital when needed, we might have to delay, curtail or eliminate one or more of our R&D programs and commercialization efforts and potentially change our growth strategy.

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

Risks Associated with our Capital Stock

Some of our executives, directors and principal stockholders can control our direction and policies, and their interests may be adverse to the interests of our other stockholders.

At December 31, 2014, Lindsay A. Rosenwald, M.D., our Chairman, President and Chief Executive Officer, beneficially owned approximately 12.4% of our issued and outstanding capital stock. At December 31, 2014, Michael S. Weiss, our Executive Vice Chairman, Strategic Development, beneficially owned approximately 14.9% of our issued and outstanding capital stock. By virtue of their holdings and membership on our board of directors, Dr. Rosenwald and Mr. Weiss may individually influence 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, several of our directors may influence the election of members to our board of directors. On February 20, 2014, Drs. Harvey, Rosenwald and Rowinsky and Messrs. Barrett, Lobell and Weiss, entered into a Shareholders' Agreement, pursuant to which they agreed that, until the end of our annual meeting held in calendar year 2016 and so long as Dr. Rosenwald and Mr. Weiss are on the proposed slate of directors to be nominated, they each will vote all of their shares of Company Common Stock in favor of electing those individuals, and only those individuals, to our board of directors whom our Nominating and Corporate Governance Committee proposes. Until that time, they also agreed to not publicly or otherwise advocate for or encourage in any way (outside of fulfilling their director duties) the election of any individual to our board of directors whom is not proposed by our Nominating and Corporate Governance Committee.

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:

- Announcements we make regarding our current product candidates, the acquisition of potential new product candidates and/or in-licensing through multiple subsidiaries;
- 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 any of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors, product manufacturers or our ability to produce TSO;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our Common Stock, regardless of our actual operating performance. Most significantly and subsequent to the release of the results from our TRUST-I clinical trial, the price of our stock dropped $4.05, or 70%, from $5.77 at October 11, 2013 to $1.72 on October 21, 2013.

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 46.5 million outstanding shares of Common Stock as of December 31, 2014, 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, in July 2013, we filed a shelf registration statement on Form S-3, which was declared effective on August 19, 2013. Under the 2013 Form S-3 and an amended At-Market Issuance Sales Agreement entered into with MLV LLC in connection therewith, or the 2013 ATM, we may offer and sell shares of Common Stock having an aggregate offering price of up to $70.0 million. As of December 31, 2014, approximately $54 million remains available for issuance under the 2013 ATM.

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

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

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

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

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

In addition, 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 foregoing 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.

On January 2, 2013, the President signed into law The American Taxpayer Relief Act of 2012. Under prior law, a taxpayer was entitled to a research credit for qualifying amounts paid or incurred on or before December 31, 2011. The Taxpayer Relief Act extended the research credit for two years to December 31, 2013. The extension of the research credit is retroactive and includes amounts paid or incurred after December 31, 2011. As a result of the retroactive extension, a benefit for qualifying amounts incurred in 2012 was recognized in the period of enactment, which was the first quarter of 2013.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices at 24 New England Executive Park, Suite 105, Burlington, MA 01803 are occupied under a lease expiring in October 2017, with an early termination clause for expiration in October 2015, which was exercised in January 2015, for approximately 3,200 square feet of space providing for rental payments of approximately $94,000 per year. Total rent expense for the reduced lease term, including the termination fee of this lease, will approximate $365,000. We took occupancy of this space in October 2012.

On December 2012, we assumed a lease from TSO Laboratories, Inc., a wholly owned subsidiary of Ovamed, for approximately 8,700 square feet of space in Woburn, MA for the purpose of establishing a manufacturing facility. Total rent expense for the lease term will approximate $590,000. Annual rental payments will approximate $118,000 and we have not yet taken occupancy of the space.

In April 2013, we entered into a three-year lease for approximately 1,500 square feet of office space in New York, NY at an average annual rent of approximately $122,000. Total rent expense for the term of this lease will be approximately $366,000. We commenced occupancy of this space in May 2013.

On October 3, 2014, we entered into a 15-year lease for office space at 2 Gaansevoort Street, New York, NY 10014, at an average annual rent of $2.7 million. Total rent expense for this facility will approximate $40.7 million. In conjunction with the lease, we entered into Desk Space Agreements with two related parties: Opus Point and TGTX, to occupy 20% and 40%, respectively, of the office space that requires them to pay their share of the average annual rent of $0.5 million and $1.1 million, respectively. The total net rent expense to us will approximate $16.3 million. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. Additionally, we reserved the right to execute desk space agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by us. We do not expect to take possession of the space until early 2016 and lease expense will commence upon occupancy of the space. This space will become our principal executive offices.

In November 2014, JMC entered into a two-year lease for 2,295 square feet of office space in Scottsdale, AZ, at an average annual rent of approximately $39,000. Total rent expense for the term of this lease will approximate $78,000. JMC took occupancy of this space in November 2014.

Item 3. Legal Proceedings.

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of our executive officers, threatened against or affecting our Company, our Company's properties or our officers or directors in their capacities as such.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

On November 17, 2011, we became a public company. Our Common Stock is listed for trading on The NASDAQ Capital Market, or NASDAQ, under the symbol "CNDO." The following table sets forth the high and low intraday sales prices of our Common Stock for each full quarterly period within the two most recent fiscal years.

	2014		2013	
	High	Low	High	Low
First quarter	$ 3.17	$ 1.95	$ 9.72	$ 4.84
Second quarter	$ 2.02	$ 1.55	$ 12.00	$ 7.55
Third quarter	$ 2.16	$ 1.48	$ 10.05	$ 6.82
Fourth quarter	$ 2.53	$ 1.52	$ 8.30	$ 1.27

Holders of Record

As of March 13, 2015, there were approximately 729 holders of record of our Common Stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders who shares may be held in trust by other entities.

Repurchases

None.

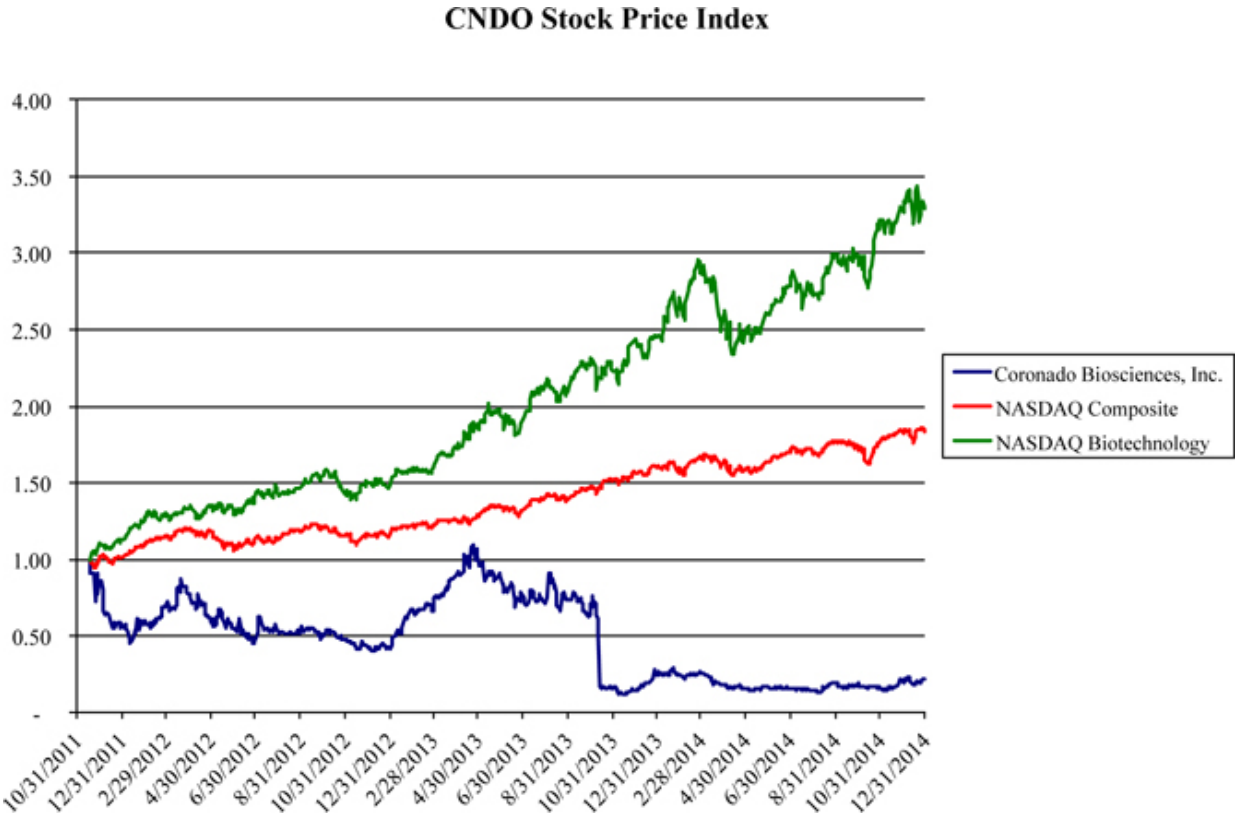
Dividends

We have never paid cash dividends and currently intend to retain our future earnings, if any, to fund the development and growth of our business.

Stock Performance Graph

The following shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our other filings under the Exchange Act or the Securities Act, except to the extent we specifically incorporate it by reference into such filing.

This graph compares the cumulative total return on our Common Stock with that of the NASDAQ Composite and the NASDAQ Biotechnology index. This chart adjusts prices for stock splits and assumes the reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.



Notes:
(1) The graph is indexed based on the stock price on November 30, 2011

Sales of Unregistered Securities

During 2014, we did not issue any equity securities that were not registered under the Securities Act, or that were not previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K of the Company.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Item 6. Selected Consolidated Financial Data.

As part of our growth strategy we have commenced and will continue to leverage our substantial biopharmaceutical business, financial and drug development expertise to invest in the acquisition, development and commercialization of novel pharmaceutical and other biomedical products. We are employing a variety of approaches and corporate structures to acquire rights to and finance a diverse portfolio of innovative pharmaceutical and biotechnology products, technologies and companies. These may include licensing, partnerships, joint ventures, and private or public spin-outs. We believe these activities will diversify our product development and, over time, may enhance shareholder value through potential royalty, milestone and equity payments, fees as well as potential product revenues. As a result, the data in the following table might not be indicative of future financial conditions and/or results of operations.

	For the Years Ended December 31,				
	2014	2013	2012	2011	2010
(In thousands except per share amounts)					
Operating expenses:					
Research and development	$ 10,239	$ 25,682	$ 17,468	$ 8,583	$ 8,341
General and administrative	10,413	10,098	8,665	5,755	900
In-process research and development	—	—	1,043	20,706	—
Loss from operations	(20,652)	(35,780)	(27,176)	(35,044)	(9,241)
Interest income	662	545	236	165	61
Interest expense	(1,338)	(1,923)	(670)	(74)	(1,535)
Change in fair value of investments	942	—	—	—	—
Other income	—	—	—	—	733
Warrant expense	—	—	—	(1,407)	—
Net loss	(20,386)	(37,158)	(27,610)	(36,360)	(9,982)
Common Stock dividend to Series A Convertible Preferred Stockholders	—	—	—	(5,861)	—
Net loss attributed to Common Stockholders	$ (20,386)	$ (37,158)	$ (27,610)	$ (42,221)	$ (9,982)
Basic and diluted net loss per common share	$ (0.56)	$ (1.22)	$ (1.27)	$ (5.51)	$ (2.24)
Weighted average common shares outstanding—basic and diluted	36,323,355	30,429,743	21,654,984	7,662,984	4,453,786
Financial Condition:					
Cash and cash equivalents	$ 49,759	$ 99,521	$ 40,199	$ 23,160	$ 14,862
Total assets	$ 89,331	$ 100,582	$ 40,992	$ 23,375	$ 14,939
Current liabilities	$ 4,077	$ 11,210	$ 5,132	$ 3,493	$ 1,559
Long-term liabilities	$ 14,731	$ 8,094	$ 13,827	$ 750	$ —
Stockholders' equity/(deficit)	$ 70,523	$ 81,278	$ 22,033	$ 19,132	$ (15,897)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information appearing elsewhere in this Form 10-K.

Since inception, we have been a biopharmaceutical company involved in the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer, namely CNDO-201 or *Trichuris suis* ova ("TSO") and CNDO-109, as more fully described below. As part of our growth strategy we have commenced and will continue to leverage our substantial biopharmaceutical business, financial and drug development expertise to invest in the acquisition, development and commercialization of novel pharmaceutical and other biomedical products. We are employing a variety of approaches and corporate structures to acquire rights to and finance a diverse portfolio of innovative pharmaceutical and biotechnology products, technologies and companies. These may include licensing, partnerships, joint ventures, and private or public spin-outs. As we seek to acquire and advance investment opportunities with high-growth potential, we are also exploring strategic options to realize value from our existing product candidates, TSO and CNDO-109. We expect to report progress with these initiatives going forward.

Our two principal pharmaceutical product candidates currently in clinical development are:

- TSO, or CNDO-201, the microscopic eggs of the porcine whipworm, for the treatment of immune-mediated diseases, such as Crohn's disease, or CD, ulcerative colitis, or UC, or autism spectrum disorder, or ASD; and

- CNDO-109, a biologic that activates natural killer, or NK, cells of the immune system to seek and destroy cancer cells, for the treatment of acute myeloid leukemia, or AML.

In October 2013, we announced that our TRUST-I study did not meet its primary endpoint of improving response which was driven by a higher-than-expected placebo response rate in patients with CDAI<290. While we are continuing to analyze the trial data, the results of this trial negatively impact the potential for successful development of TSO.

In November 2013, Dr. Falk Pharma GmbH ("Falk"), our development partner, informed us that an independent data monitoring committee had conducted a second interim analysis of data from its Phase 2 clinical study for CD known as TRUST-II and recommended that the trial be stopped due to lack of efficacy and noted no safety concerns. Falk adopted the committee's recommendations and discontinued the study.

In February 2014, we repaid in full our term loan with Hercules Technology Growth Capital, Inc. (the "Hercules Note") and entered into a new promissory note ("IDB Note") with Israel Discount Bank of New York ("IDB"), under which we can borrow up to $15.0 million. At December 31, 2014, the amount of debt outstanding under the IDB Note was $14.0 million. (See Note 10 of Notes to Consolidated Financial Statements).

In March 2014, we submitted an Investigational New Drug Study to the U.S. Food and Drug Administration (the "FDA") for the treatment of autism in 20 pediatric patients. In May 2014, we initiated a Phase 2a clinical trial of TSO for the treatment of 20 pediatric patients with autism spectrum disorder at multiple sites in the United States.

In March 2014, we abandoned our plans to buildout the Woburn, MA manufacturing facility and closed our New York, NY office. As a result, we commenced marketing both facilities for sub-lease. In April 2014, we entered into a sub-lease arrangement for our New York, NY office for the remaining term of the lease. During the year ended December 31, 2014, we recorded a lease impairment and fixed asset impairment charge of $0.7 million. (See Note 7 of Notes to Consolidated Financial Statements).

In March 2014, we terminated our Research Agreement with Freie Universität Berlin ("FU Berlin") and recorded a one-time charge of $0.2 million related to the contract termination in our Consolidated Statements of Operations. (See Note 15 of Notes to Consolidated Financial Statements).

On March 17, 2014, we made a $250,000 investment in a third-party medical device company developing a laser device to treat migraine headaches. The investment represents a 35% ownership position in such company. We elected the fair value option to record this investment. (See Note 9 of Notes to Consolidated Financial Statements).

Also on March 17, 2014, we provided a $50,000 bridge loan to an emerging specialty pharmaceutical company developing, marketing and distributing epilepsy drugs. The bridge loan was payable in 90 days, accrued interest at a rate of 8% and was secured by the assets of such company. We recorded this bridge loan in short-term investments. As of December 31, 2014, the loan remained outstanding and on March 4, 2015 it was paid in full.

On April 18, 2014, we paid $243,000 to acquire an option to purchase ("Option") the exclusive rights to a topical product, 1UO, used in the treatment of Hand-Foot Syndrome owned by a third party and on August 12, 2014, we paid $50,000 to extend this Option for a total purchase price of $293,000. On September 30, 2014, the Option expired and we recognized a loss of $293,000, which reflects the change in the fair value of the Option. (See Note 9 of Notes to Consolidated Financial Statements).

In September 2014, we formed a blank check company in the Cayman Islands, CB Pharma Acquisition Corp. ("CB Pharma"), for the purpose of entering into a business combination with one or more businesses or entities, with a current focus in the specialty pharmaceuticals and generic drug industries, among others. Upon the formation of CB Pharma, we purchased 1,150,000 insider shares of CB Pharma for $25,000 in a private placement. In December 2014, CB Pharma closed its initial public offering ("IPO"), including an over-allotment exercise, and a private placement raising net proceeds of $42.9 million, to be held in trust until such time that a business combination is consummated. In conjunction with the IPO, we purchased 265,000 ordinary shares of CB Pharma at $10.00 per share for an aggregate purchase price of $2.7 million in a private placement. Each ordinary share is entitled to a right of one-tenth of a share upon an initial business combination and a warrant of one-half an ordinary share to be exercised at $11.50 per share, are non-redeemable, and may be exercised the later of the completion of an initial business combination or 12 months following the prospectus date of December 12, 2014. None of the shares we purchased have liquidation rights. Our investment in CB Pharma, at December 31, 2014, represents approximately 23% ownership in CB Pharma. We elected the fair value option to record this long-term investment and recorded a change in the fair value of this investment of $1.2 million based upon an independent valuation. (See Note 9 of Notes to Consolidated Financial Statements).

In October 2014, the Company formed Journey Medical Corporation ("JMC"), a wholly owned subsidiary of the Company. JMC will acquire and license dermatology products for acne, steroid responsive dermatoses, pigmentation and antifungals for promotion to dermatologists and pediatricians. JMC is headquartered in Scottsdale, AZ, and as of December 31, 2014, had four full-time employees.

Subsequent to December 31, 2014, we have continued to make significant progress implementing our growth strategy, commencing in January 2015 with the in-licensing of a topical product, 1UO, used in the treatment of Hand-Foot Syndrome, by our subsidiary Coronado SO. In February 2015 we purchased an exclusive license to intravenous formulation of IV Tramadol and, in March 2015, we announced the formation of our subsidiary Checkpoint Therapeutics, Inc. ("Checkpoint") which will focus on the development of a portfolio of fully human immuno-oncology targeted antibodies generated in the laboratory at the Dana-Farber Cancer Institute ("Dana-Farber"). (Note 18 of Notes to Consolidated Financial Statements).

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to research and development, accrued expenses, stock-based compensation and fair value of investments. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Form 10-K. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, reviewing the terms of our license agreements, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses as of December 31, 2014 include fees to:

- contract research organizations, or CROs, and other service providers in connection with clinical studies;
- investigative sites in connection with clinical studies;
- contract manufacturers in connection with production of clinical trial materials;
- vendors in connection with the preclinical development activities; and
- licensors for the achievement of milestone-related events.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. To date, our estimates have not materially differed from actual costs. Expenses related to annual license fees are accrued on a pro rata basis throughout the year.

Stock-Based Compensation

We expense stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and considering estimated pre-vesting forfeiture rates. For stock-based compensation awards to non-employees, we re-measure the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change.

Determining the appropriate fair value of stock-based awards requires the use of subjective assumptions. Prior to November 17, 2011 in the absence of a public trading market for our Common Stock, we conducted periodic assessments of the valuation of our Common Stock. These valuations were performed concurrently with the achievement of significant milestones or with a significant financing. We use a Black-Scholes option-pricing model to determine the fair value of stock options. The determination of the grant date fair value of options using an option-pricing model is affected by our estimated Common Stock fair value as well as assumptions regarding a number of other subjective variables. These variables include the fair value of our Common Stock, our expected stock price volatility over the expected term of the options, stock option exercise and cancellation behaviors, risk-free interest rates, and expected dividends, which are estimated as follows:

- We utilized the public trading price of our Common Stock.

- Expected Term. Due to the limited exercise history of our own stock options, we determined the expected term based on the stratification of option holder groups. Our employee options meet the criteria for the Simplified Method under SAB 107 while the expected term for our non-employees is the remaining contractual life for both options and warrants.

- Volatility. As we have a very limited trading history for our Common Stock, the expected stock price volatility for our Common Stock was estimated by incorporating two years of our historical volatility and the average historical price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. Our historical volatility is weighted with that of the peer group and that combined historical volatility is weighted 80% with a 20% weighting of our implied volatility, which is obtained from traded options of our stock. We intend to continue to consistently apply this process using the same or similar public companies until we have sufficient historical information regarding the volatility of our own Common Stock that is consistent with the expected life of our options. Should circumstances change such that the identified companies are no longer similar to us, more suitable companies whose share prices are publicly available would be utilized in the calculation.

- Risk-free Rate. The risk-free interest rate is based on the yields of United States Treasury securities with maturities similar to the expected term of the options for each option group.

- Dividend Yield. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period in which estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class and historical experience. Actual results, and future changes in estimates, may differ substantially from our current estimates.

For the years ended December 31, 2014, 2013, and 2012, stock-based compensation expense was $5.5 million, $5.9 million, and $3.6 million, respectively. As of December 31, 2014, we had approximately $1.2 million of total unrecognized compensation expense, related to unvested stock options granted to employees and non-employees, which we expect to recognize over a weighted-average period of approximately 0.6 years.

If any of the assumptions used in a Black-Scholes model changes significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously.

Restricted Stock

We granted shares of restricted Common Stock to certain employees and members of our board of directors during 2013 and 2014. These awards vest upon both the passage of time as well as the achievement of certain pre-defined market conditions. For those awards which vest based upon the passage of time, we determined the fair value of the awards using our stock price on the date of grant. For those awards which vest based on pre-defined market conditions, we determined the fair value for these awards using a Monte Carlo Simulation pricing model with the following assumptions:

- Expected Term. The contractual life for restricted stock issuance agreements is 5 years, which coincides with the vesting period.

- Volatility. As we have a very limited trading history for our Common Stock, the expected stock price volatility for our Common Stock was estimated by incorporating two years of our historical volatility and the average historical price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. Our historical volatility is weighted with that of the peer group and that combined historical volatility is weighted 80% with a 20% weighting of our implied volatility, which is obtained from traded options of our stock.

- Risk-free Rate. The risk-free interest rate is based on the yields of United States Treasury securities with maturities similar to the expected term of the restricted stock issuance agreement.

For the years ended December 31, 2014 and 2013, compensation expense recognized associated with these restricted stock awards was $4.0 million and $66,000, respectively, using the straight-line method. As of December 31, 2014, we had approximately $15.2 million of total unrecognized compensation expense related to these awards, which we expect to recognize over a weighted-average period of approximately 3.0 years. No expense was recorded during 2012.

Investments at Fair Value

We elected the fair value option for our expired short-term investment of $0.3 million to acquire the Option described above, our long-term investment of $0.2 in a third-party company developing a laser device to treat migraine headaches, and our investment in CB Pharma of $2.7 million, with a fair value of $3.9 million, as it best represents the economics and the fair value of these instruments. We have various processes and controls in place to ensure that fair value is reasonably estimated. A model validation policy governs the use and control of valuation models, established by independent consultants, to be used to estimate fair value.

While we believe our valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

The decision to elect the fair value option, which is irrevocable once elected, is determined on an instrument-by-instrument basis and applied to the entire instrument. The net gains or losses, if any, on an investment for which the fair value option has been elected are recognized as a change in fair value of investments, net in the Consolidated Statements of Operations.

Results of Operations

General

To date, we have not generated any revenues from operations and, at December 31, 2014, we had an accumulated deficit of $141.7 million primarily as a result of research and development expenses, purchases of in-process research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our current product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant revenues.

Research & Development Expenses

Conducting research and development has been central to our business. For the years ended December 31, 2014, 2013 and 2012 research and development expenses were $10.2 million, $25.7 million, and $17.5 million, respectively. Noncash, stock-based compensation expense included in research and development in 2014, 2013 and 2012 was $1.1 million, $3.0 million and $3.6 million, respectively. Research and development expenses consist primarily of:

- employee-related expenses, which include salaries and benefits, and rent expense;

- noncash stock-based compensation expense;

- license fees and milestone payments related to in-licensed products and intellectual property;

- expenses incurred under agreements with CROs, investigative sites and consultants that conduct or provide other services relating to our clinical trials and our preclinical activities;
- the cost of acquiring clinical trial materials from third party manufacturers; and
- costs associated with non-clinical activities, patent filings and regulatory filings.

We expect to continue to incur expenses related to our research and development activities for the foreseeable future as we develop our existing product candidates and potentially acquire new product candidates. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, our research and development expenses might increase in the future. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential commercialization of any late-stage product candidates and, in the event one or more of these product candidates receive regulatory approval, to fund the launch of the product.

For the years ended December 31, 2014, 2013 and 2012, direct, external development costs incurred for our TSO product development program were $2.6 million, $12.2 million, and $10.9 million, respectively. For the years ended December 31, 2014, 2013 and 2012, direct, external development costs incurred for our CNDO-109 product development program were $2.1 million, $2.2 million, and $1.9 million, respectively.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development expenses. For the years ended December 31, 2014, 2013, and 2012, general and administrative expenses were $10.4 million, $10.1 million, and $8.7 million, respectively. Noncash, stock-based compensation expense included in general and administrative expenses in 2014, 2013 and 2012 was $4.4 million, $2.9 million and $2.1 million, respectively. We anticipate general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded research and development activities;
- support of business development activities; and
- an expanding infrastructure and increased professional fees and other costs associated with the regulatory requirements and increased compliance associated with being a public reporting company.

Comparison of Years Ended December 31, 2014 and 2013

	For the year ended December 31,		Variance	
	2014	2013	$	%
Operating expenses:				
Research and development	$ 10,239	$ 25,682	$ (15,443)	(60)%
General and administrative	10,413	10,098	315	3%
Loss from operations	(20,652)	(35,780)	15,128	42%
Interest income	662	545	117	21%
Interest expense	(1,338)	(1,923)	585	30%
Change in fair value of investments	942	—	942	100%
Net loss	$ (20,386)	$ (37,158)	$ 16,772	45%

Research and development expenses decreased $15.4 million, or 60%, from $25.7 million in the year ended December 31, 2013 to $10.2 million in the year ended December 31, 2014. This decrease was primarily due to a $9.6 million reduction in TSO product development costs related to the wind down of Phase 2 of the TRUST-I trial and reduced development activities. In addition, personnel costs decreased by $3.6 million which was primarily composed of reductions of $1.7 million in salary, benefits as a result of a reduction in headcount, bonus and travel expense and $1.9 million in stock-based compensation expense, primarily due to a decrease in headcount as well as a reduction in the unvested mark-to-market value of our non-employee option grants. In addition, consulting expenses decreased by $1.7 million primarily due to a reduction in consulting expense of $1.3 million related to the design of our manufacturing facility and product development costs also decreased by $1.3 million. These decreases in expense were partially offset by a $0.7 million charge related to the decision to delay manufacturing of TSO in the Woburn, MA facility. We expect to incur expenses related to our research and development efforts going forward with existing product candidates as well as potentially acquired new products.

General and administrative expenses increased $0.3 million, or 3%, from $10.1 million in the year ended December 31, 2013 to $10.4 million in the year ended December 31, 2014, largely due to a $1.5 million increase in stock-based compensation expense due to restricted stock grants made to our Chief Executive Officer, our Executive Vice President of Strategic Development and the independent members of our board of directors in the first quarter of 2014 as well as $0.9 million related to professional fees incurred in connection with our business development activities. This increase was partially offset by a $2.0 million decrease in personnel costs primarily resulting from the November 2013 termination of certain personnel.

Interest expense in 2014 primarily relates to interest on the Hercules Note, which included a prepayment fee of $0.3 million, representing 2% of the outstanding debt and interest on the IDB Note. The increase in interest income in 2014 compared to the same period last year was primarily due to on average higher cash balances for the period. The change in fair value of investments primarily relates to the increase in value of our investment in CB Pharma of $1.2 million, offset by our decision not to exercise the Option of $0.3 million.

Comparison of Years Ended December 31, 2013 and 2012

	For the year ended December 31,		Variance	
	2013	2012	$	%
Operating expenses:				
Research and development	$ 25,682	$ 17,468	$ 8,214	47%
General and administrative	10,098	8,665	1,433	17%
In-process research and development	—	1,043	(1,043)	NM
Loss from operations	(35,780)	(27,176)	8,604	32%
Interest income	545	236	309	131%
Interest expense	(1,923)	(670)	1,253	187%
Net loss	$ (37,158)	$ (27,610)	$ 9,548	35%

NM–Not meaningful

Research and development expenses increased $8.2 million, or 47%, from the year ended December 31, 2012 to the year ended December 31, 2013. This increase was primarily due to a $3.0 million increase related to the manufacturing development of TSO and $5.4 million of increased external development costs also related to TSO. In 2013, we incurred $9.4 million related to our Phase 2 study for TSO in CD, $0.9 million related to the development of TSO in other indications and $0.2 million in sponsored research. In 2012, we incurred $4.0 million of expense related to our Phase 2 study for TSO and $0.3 million for the development of TSO in other indications. In 2013, we incurred a $0.3 million milestone related charge pursuant to our sublicense agreement with Ovamed; while in 2012, we also incurred a $3.3 million of milestone-related charges in connection with our collaboration agreement with Falk as well as the $0.2 million milestone-related charge pursuant to our agreement with Ovamed. In 2013, we purchased $1.0 million of TSO clinical supply from Ovamed compared with a similar purchase of $2.0 million in 2012. Personnel costs increased $3.5 million in 2013, primarily due to $1.1 million in severance and $0.7 million related to increased staffing. In addition, in 2013, stock-based compensation increased $1.5 million, of which $0.7 million related to the modification of options and expense of options to our former CEO in 2013 and other employees. In 2012, stock-based compensation expense increased $0.5 million, of which $0.3 million related to the modification of options issued to certain of our executive officers (See Note 15 of Notes to Consolidated Financial Statements). CNDO-109 development costs increased by $0.5 million primarily due to the commencement of the Phase 1/2 clinical trial.

General and administrative expenses increased $1.4 million, or 17%, in the year ended December 31, 2013 as compared to the year ended December 31, 2012. The increase in general and administrative expenses consisted primarily of a $0.8 million increase in stock compensation expense, including $0.7 million related to the modification and acceleration of options and the expense of options to our former CEO and other executives. Personnel-related costs increased $0.9 million, primarily due to severance related to the elimination of certain executive positions. (See Note 15 of Notes to the Consolidated Financial Statements).

In 2012, we acquired from Ovamed manufacturing rights for TSO in North America, South America and Japan known as the “Coronado Territory” and agreed to pay Ovamed $1.5 million, which obligation was recorded as in-process research and development expense in 2012 at its estimated net present value of $1.0 million. In 2013, we recorded in interest expense $0.1 million of accretion related to this obligation resulting in a net present value of $1.2 million. This liability is included in other long-term liabilities at December 31, 2012 and 2013, the $0.5 million payable in December 2014 is recorded in accrued expenses and $0.7 million is recorded in other long-term liabilities on the consolidated balance sheets.

The increase in interest income in 2013 compared to the same period last year was primarily due to higher cash balances.

Interest expense increased $1.3 million, or 187% from the year ended December 31, 2012 to the year ended December 31, 2013. This increase was primarily due to $1.9 million of interest on the Hercules Note in 2013 compared to $0.6 million in 2012 as the Hercules Note commenced in August 2012.

Liquidity and Capital Resources

To date, we have funded our operations through the sale of debt and equity securities, aggregating $187.0 million of net proceeds. At December 31, 2014, we had cash and cash equivalents of $49.8 million, plus marketable securities of $20.0 million and restricted cash of $14.6 million, of which $14.0 million is securing the IDB Note and $0.6 million of which is securing a letter of credit used as a security deposit for the New York, NY lease that became effective on October 3, 2014.

In July 2013, we filed a shelf registration statement on Form S-3, which was declared effective on August 19, 2013. Under the 2013 Form S-3 and amended At Market Issuance Sales Agreement entered into with MLV LLC, in connection therewith (the "2013 ATM"), we may offer and sell shares of Common Stock having an aggregate offering price of up to $70.0 million. As of December 31, 2013, approximately $54.0 million remains available under the 2013 ATM. On September 30, 2013, our stockholders voted to approve an amended and restated certificate of incorporation to increase the number of authorized shares of our capital stock from 65,000,000 shares to 115,000,000 shares and to increase the number of authorized shares of our Common Stock from 50,000,000 to 100,000,000. In February 2014, the Company repaid the Hercules Note in full and entered into the IDB Note in the amount of $15.0 million (see Note 10 of Notes to Consolidated Financial Statements). Early payment of the Hercules Note approximated $14.0 million consisting of principal of $13.2 million, end of term charge of $0.4 million, a prepayment fee of $0.3 million and interest of $0.1 million. Prior to repayment, in January 2014, the Company made a scheduled principal payment of $0.5 million on the Hercules Note.

We may require additional financing to fully develop, and prepare regulatory filings and obtain regulatory approvals for our existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for our potential products, sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt securities. We believe that our current cash is sufficient to fund operations for at least the next twelve months. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We may seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding, particularly subsequent to the negative results from our TRUST-I clinical trial, may not be available to us on acceptable terms or at all. If adequate funds are not available to us when needed, we may be required to delay, curtail or eliminate one or more of our research and development programs and, potentially, delay our growth strategy.

Cash Flows for the Three Years Ended December 31, 2014, 2013 and 2012

	For the Year Ended December 31,		
(In thousands)	**2014**	**2013**	**2012**
Statement of Cash Flows Data:			
Total cash provided by (used in)/provided by:			
Operating activities	$ (16,334)	$ (29,646)	$ (23,194)
Investing activities	(23,273)	(188)	(279)
Financing activities	(10,155)	89,156	40,512
(Decrease)/increase in cash and cash equivalents	$ (49,762)	$ 59,322	$ 17,039

Operating Activities

Net cash used in operating activity decreased by $13.3 million from the year ended December 31, 2013 to the year ended December 31, 2014, primarily due a $16.7 million decrease in net loss and an impairment charge of $0.7 million. Partially offset by a $0.9 million change in fair value of our long-term investments, a $2.4 million reduction in accounts payable and accrued expenses, a $0.4 related to the repayment of debt and a $0.4 million reduction in stock compensation expense.

Net cash used in operating activities increased $6.5 million from the year ended December 31, 2012 to the year ended December 31, 2013. The increase was primarily due to the increase in our net loss of $9.5 million, which was partially offset by the increase in stock-based compensation of $2.3 million. The increase in stock-based compensation was primarily due to an increase in the number of stock options outstanding, the impact of our higher stock price on the value of options granted to employees during 2013 and the accelerations and modification to options as a result of executive terminations. Other factors contributing to the change were a $1.4 million increase in accounts payable and accrued expenses and a $1.0 million decrease in the amount of acquired in-process research and development which resulted from a noncash expense in connection with our acquisition of TSO manufacturing rights from Ovamed in 2012.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2014, relates to our $20.0 million investment in marketable securities, our formation and interest in CB Pharma for $2.7 million, our $0.2 million investment in a third party developing a laser device for the treatment of migraine headaches, and our expired Option of $0.3 million.

Net cash used in investing activities was $0.2 million in 2013 and relates to payments for construction of our Woburn, MA manufacturing facility and the purchase of equipment for our office in Burlington, MA.

Net cash used in investing activities was $0.3 million in 2012 and consisted primarily of a $225,000 deposit for leasehold improvements for our new manufacturing facility and $54,000, related to the purchase of office furniture and equipment and leasehold improvements.

Financing Activities

Net cash used in financing activities of $10.2 million for the year ended December 31, 2014, reflects $14.0 million in proceeds from the IDB Note offset by a transfer of $14.0 million to restricted cash to secure the IDB Note, $13.7 million from the repayment of the Hercules Note as well as $0.6 million to restricted cash to secure a line of credit in connection with the New York, NY lease. These reductions in cash were partially offset by $4.1 million related to proceeds from issuances of Common Stock.

Net cash provided by financing activities of $89.2 million in the year ended December 31, 2013 consisted primarily of $92.4 million in proceeds from the issuance of stock in connection with our 2013 and 2012 at the market offerings, offset by $1.9 million in Common Stock issuance costs and our payment of $1.3 million in satisfaction of our principal payment obligations under the Hercules Note.

Net cash provided by financing activities of $40.5 million in the year ended December 31, 2012 reflected $26.4 million of net proceeds from our underwritten public offering and $14.7 million of net proceeds from a $15.0 million term loan from Hercules, offset by our payment of $750,000 in satisfaction of our obligations under the Paramount Capital Partners Note.

Contingent Contractual Payments

The following table summarizes our contractual obligations as of December 31, 2014, excluding amounts related to contingent milestone payments, as described below.

	Payments due by period				
($ in thousands)	**Total**	**Less than 1 year**	**1 to 3 years**	**4 to 5 years**	**After 5 years**
Note Payable and interest (1)	$ 14,824	$ 14,574	$ 250	$ —	$ —
Operating leases (2)	41,533	461	5,195	4,994	30,883
Annual sublicense fees (3)	12,700	4,950	1,750	750	5,250
Purchase and other obligations	2,996	2,893	103	—	—
Total	$ 72,053	$ 22,878	$ 7,298	$ 5,744	$ 36,133

(1) Relates to the IDB Note and commitment to loan CB Pharma up to $0.5 million for working capital.

(2) Relates to two New York, NY leases, Scottsdale, AZ, as well as Burlington, MA and Woburn, MA leases. For the New York, NY lease that commences in 2016, we have in place desk share agreements that reimburse us for $24.4 million, or 60%, of the $40.7 million obligation through the term of our lease.

(3) Annual sublicense fees are projected through 2025 and include payments to Ovamed, Falk and University College of London Business PLC, or UCLB.

As of December 31, 2014, approximately $2.1 million of contingent contractual payments are reflected in accrued expenses and in purchase and other obligations in the table above.

In February 2014, we repaid in full the Hercules Note and entered into the IDB Note, under which we can borrow up to $15.0 million. At December 31, 2014, the amount of debt outstanding under the IDB Note was $14.0 million. (See Note 10 of Notes to the Consolidated Financial Statements.)

On October 3, 2014, we entered into a 15-year lease for office space in New York, NY at an average annual rent of $2.7 million. Also, on October 3, 2014, we entered into a Desk Space Agreements with each of Opus Point Partners Management, LLC ("OPPM") and TG Therapeutics, Inc. ("TGTX"), to occupy 20% and 40%, respectively, of the New York, NY office space that requires them to pay their share of the average annual rent of $0.5 million and $1.1 million, respectively. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. Additionally, we have reserved the right to execute additional desk space agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by us. We do not expect to take possession of the space until early 2016 and lease expense will commence upon occupancy of the space. The lease was executed to further our business strategy, which includes forming additional subsidiaries and/or affiliate companies. Mr. Weiss is Executive Chairman, Interim Chief Executive Officer and a stockholder of TGTX. The lease is subject to early termination by us, or in circumstances including events of default, the landlord, and includes a five-year extension option in our favor.

In April 2013, we entered into a three-year lease for approximately 1,500 square feet of office space in New York, NY at an average annual rent of approximately $122,000. Total rent expense for the term of this lease was approximately $366,000. We commenced occupancy of this space in May 2013. In March 2014, we closed the New York, NY office and entered into a sub-lease with a third party to occupy the space conterminously with our lease agreement. In November 2014, our sub-tenant vacated the space. As a result, we commenced activities to sub-lease this facility.

In July 2012, we entered into a five-year lease for approximately 3,200 square feet of office space in Burlington, MA at an average annual rent of approximately $94,000. The Company took occupancy of this space in October 2012. On December 31, 2014, we exercised an early termination clause in the lease for a fee of $81,600 payable in January 2015, reducing the lease term to three years.

Pursuant to the Second Amendment and Agreement, dated as of December 21, 2012, by and between us and Ovamed, we entered into an Assignment and Assumption of Lease with TSO Laboratories, Inc., a wholly owned subsidiary of Ovamed, for approximately 8,700 square feet in Woburn, MA for the purpose of establishing a manufacturing facility. Total rent expense for the five-year lease term was to approximate $590,000 at an average annual rate of $118,000. Our contractual leasehold improvement costs, as amended in 2013, associated with this lease approximate $373,000. An initial deposit of $225,000 for these costs was made in December 2012 and was included in other assets in the December 31, 2012 on the consolidated balance sheets at December 31, 2013, this amount is in included in Construction in Progress on the consolidated balance sheets. In March 2014, we abandoned our plans to buildout the Woburn, MA manufacturing facility. As a result, we commenced marketing the facility for sub-lease.

In December 2012, we entered into the Second Amendment to our supply agreement with Ovamed which amended certain provisions of our exclusive sublicense agreement and our manufacturing and supply agreement and provided for certain additional agreements with Ovamed (the "Manufacturing Agreement"). This agreement provides us with the exclusive right to manufacture TSO for sale in the Coronado Territory. Under this agreement, we agreed to pay Ovamed $1.5 million, in three equal annual installments, which is included in annual license fees.

Our purchase and other obligations are primarily associated with our clinical trials, including $1.5 million for services associated with our planned Phase 1/2 CNDO-109 trial, $0.8 million associated with our planned autism trial, $0.5 million for our Phase 2 trial evaluating TSO as a treatment for CD, and $0.2 for our manufacturing collaboration with Ovamed.

Off-Balance Sheet Arrangements

We do not have any financings or other relationships with unconsolidated entities or other persons.

Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of December 31, 2014, we had marketable securities of $20.0 million, consisting of U.S. Treasury Bills and mutual funds. As of December 31, 2013, we had no marketable securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

The IDB Note bears an interest rate per annum of the rate payable on the pledge account, currently set at 0.75% plus a margin of 1.50%. To the extent the interest payable on the pledge account increases, we would pay higher interest on the outstanding debt.

Net Operating Loss Tax Carry-Forwards

As of December 31, 2014, we had federal net operating loss carryforwards of approximately $101.4 million to offset future federal income taxes which expire beginning in 2026 and state net operating loss carryforwards of $50.7 million to offset future state taxes which expire beginning in 2031. Current federal and state tax laws include substantial restrictions on the utilization of net operating loss and tax credits in the event of an ownership change. Even if the carryforwards are available, they may be subject to substantial annual limitations, due to ownership change limitations provided by the Internal Revenue Code of 1986 as amended, or IRC and similar state provisions. At December 31, 2014 and 2013, we recorded a 100% valuation allowance against our deferred tax assets, as our management believes it is more likely than not that they will not be realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination. Approximately $1.8 million of the federal net operating loss carryforward and $1.6 million of the state net operating loss carryforwards will result in an increase to additional paid-in capital if and when these carryforwards are used to reduce income taxes payable.

Recently Issued Accounting Pronouncements

See Note 2 of Notes to the Consolidated Financial Statements for a discussion of recent accounting standards and pronouncements.

Overview

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Refer to the information above in Item 7.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item is set forth in the consolidated financial statements and notes thereto beginning at page F-1 of this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) are designed only to provide reasonable assurance that they will meet their objectives. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of December 31, 2014, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Internal Control Over Financial Reporting

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making the assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control – Integrated Framework (2013)*.

Based on our assessment, our management has concluded that, as of December 31, 2014, our internal controls over financial reporting were effective based upon those criteria.

Attestation Report of Registered Public Accounting Firm

The effectiveness of our internal controls over financial reporting as of December 31, 2014 has been audited by our independent registered accounting firm, EisnerAmper LLP, as stated in their attestation report, which is included on page F-3 herein.

Changes in Internal Controls over Financial Reporting.

There were no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item concerning our executive officers and directors is incorporated by reference from the sections captioned "Election of Directors Corporate Governance Matters" and "Section 16(a) Beneficial Ownership Reporting Compliance" contained in our proxy statement related to the 2015 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2015 which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

The information required by this Item concerning the identification of our executive officers is set forth at the end of Part I of this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to the information under the sections captioned "Executive Compensation and Other Matters," "Compensation Discussion and Analysis," "Summary Compensation Table," "Grants of Plan-Based Awards," "Outstanding Equity Awards at 2014 Fiscal Year-End," "Option Exercises and Stock Vested," "Director Compensation," "Compensation Committee Interlocks and Insider Participation" and "Transactions with Related Persons" in the proxy statement related to our 2015 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2015.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth the indicated information as of December 31, 2014 with respect to our equity compensation plans:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by stockholders	2,164,365	$ 4.69	1,267,720
Equity compensation plans not approved by stockholders	—	$ —	—
Total	2,164,365		1,267,720

Our equity compensation plans consist of the Employee Stock Purchase Plan, Coronado Biosciences, Inc. 2007 Stock Incentive Plan and the Coronado Biosciences, Inc. 2013 Stock Incentive Plan, all of which were approved by our stockholders. We do not have any equity compensation plans or arrangements that have not been approved by our stockholders.

The other information required by this Item is incorporated by reference to the information under the section captioned "Security Ownership of Certain Beneficial Owners and Management" contained in the proxy statement related to our 2015 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2015.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to the information under the section captioned "Transactions with Related Persons" and "Corporate Governance Matters" in the proxy statement related to our 2015 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2015.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference to the information under the section captioned "Audit Committee Report" in the proxy statement related to our 2015 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2015.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements.

The following financial statements are filed as part of this report:

(b) Exhibits.

		Incorporated by Reference (Unless Otherwise Indicated)			
Exhibit Number	**Exhibit Title**	**Form**	**File**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	10-12G	000-54469	3.1	July 15, 2011
3.2	First Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	10-12G	000-54469	3.2	July 15, 2011
3.3	Certificate of Designation, Preferences and Rights of the Series B Preferred Stock.	10-12G	000-54469	3.3	July 15, 2011
3.4	Certificate of Designation, Preferences and Rights of the Series C Preferred Stock.	10-12G	000-54469	3.4	July 15, 2011
3.7	Second Amended and Restated Bylaws of the Registrant.	8-K	—	3.7	October 31, 2013
3.8	Second Certificate of Amendment of Amended and Restated Certificate of Incorporation, as amended.	10-K	—	3.8	March 14, 2014
4.1	Form of Common Stock Certificate.	10-12G	000-54469	4.1	July 15, 2011
4.2	Form of Series A Preferred Stock Certificate.	10-12G	000-54469	4.2	July 15, 2011
4.3	Form of Series B Preferred Stock Certificate.	10-12G	000-54469	4.3	July 15, 2011
4.4	Form of Series C Preferred Stock Certificate.	10-12G	000-54469	4.4	July 15, 2011
4.5	Form of Warrant for the purchase of shares of Common Stock issued by the Registrant in connection with the 2008 bridge financing.	10-12G	000-54469	4.5	July 15, 2011

4.6	Form of Warrant for the purchase of shares of Common Stock issued by the Registrant in connection with the 2009 bridge financing.	10-12G	000-54469	4.6	July 15, 2011
4.7	Form of Warrant for the purchase of shares of Common Stock issued by the Registrant in connection with the Series A financing.	10-12G	000-54469	4.7	July 15, 2011
4.8	Form of Series C Convertible Preferred Stock Purchase Warrant issued by the Registrant in connection with the 2011 Series C financing.	10-12G	000-54469	4.8	July 15, 2011
4.10	Form of Consultant/Agent Warrant to Purchase Common Stock.	10-12G	000-54469	4.10	July 15, 2011
4.11	Warrant to purchase Common Stock issued by the Registrant in connection with the 2012 secured loan facility with Hercules Technology Growth Capital, Inc.	8-K	—	4.10	August 29, 2012
10.1	Form of Note Purchase Agreement relating to the 2008 bridge financing.	10-12G	000-54469	10.1	July 15, 2011
10.2	Form of Note Purchase Agreement relating to the 2009 bridge financing.	10-12G	000-54469	10.2	July 15, 2011
10.3	Form of Subscription Agreement relating to the initial Series A financing.	10-12G	000-54469	10.3	July 15, 2011
10.4	Form of Subscription Agreement relating to the second Series A financing.	10-12G	000-54469	10.4	July 15, 2011
10.5	Form of Subscription Agreement relating to the Series C financing.	10-12G	000-54469	10.5	July 15, 2011
10.6	Form of Consent and Support Agreement.	10-12G	000-54469	10.6	July 15, 2011
10.7	Letter Agreement, dated April 29, 2011, by and between Manchester Securities Corp. and the Registrant.	10-12G	000-54469	10.7	July 15, 2011
10.8	Coronado Biosciences, Inc. 2007 Stock Incentive Plan.#	10-12G	000-54469	10.8	July 15, 2011
10.9	Form of 2007 Stock Incentive Plan and Award Agreement.#	10-12G	000-54469	10.9	July 15, 2011
10.10	Exclusive Sublicense Agreement, effective as of December 12, 2005, by and between Ovamed GmbH & Co KG and Collingwood Pharmaceuticals, Inc.	10-12G	000-54469	10.10	July 15, 2011
10.11	Manufacturing and Supply Agreement, dated March 29, 2006, by and among Collingwood Pharmaceuticals, Inc. and Ovamed GmbH.†	10-12G	000-54469	10.11	July 15, 2011
10.12	License Agreement, dated November 5, 2007, by and between UCL Business PLC and the Registrant.	10-12G	000-54469	10.12	July 15, 2011

10.13	Letter Agreement, dated November 8, 2007, by and between Asphelia Pharmaceuticals, Inc. and Ovamed GmbH.†	10-12G	000-54469	10.13	July 15, 2011
10.14	Amendment No. 1 to License Agreement, effective as of September 30, 2009, by and between the Registrant and UCL Business PLC.	10-12G	000-54469	10.14	July 15, 2011
10.15	Master Contract Services Agreement, effective as of April 1, 2010, by and between the Registrant and Progenitor Cell Therapy, LLC.†	10-12G	000-54469	10.15	July 15, 2011
10.16	Term Sheet in causa Ovamed/Asphelia, dated June 8, 2010, by and between Ovamed GmbH and Asphelia, Inc.†	10-12G	000-54469	10.16	July 15, 2011
10.17	Amendment and Agreement, dated January 7, 2011, by and among Asphelia Pharmaceuticals, Inc., the Registrant and Ovamed GmbH.†	10-12G	000-54469	10.17	July 15, 2011
10.18	Asset Purchase Agreement, dated as of January 7, 2011, by and between the Registrant and Asphelia Pharmaceuticals, Inc.	10-12G	000-54469	10.18	July 15, 2011
10.19	Employment Agreement, dated as of March 21, 2011, by and among the Registrant and Bobby W. Sandage, Jr., Ph.D.#	10-12G	000-54469	10.19	July 15, 2011
10.21	Employment Agreement, dated as of May 16, 2011, by and between the Registrant and Dale Ritter. #	10-12G	000-54469	10.21	July 15, 2011
10.24	Consulting Agreement, entered into as of September 21, 2010, by and between the Registrant and Eric Rowinsky, M.D.#	10-12G	000-54469	10.24	July 15, 2011
10.25	Form of Indemnification Agreement by and between the Registrant and its officers and directors.	10-12G	000-54469	10.25	July 15, 2011
10.26	Lease Agreement dated May 26, 2011 relating to the Registrant's premises located at 15 New England Executive Park, Burlington, Massachusetts 01803.	10-12G	000-54469	10.26	July 15, 2011
10.27	Master Contract Services Agreement, as of March 12, 2008, by and between the Registrant and BioReliance Corporation.	10-12G	000-54469	10.27	September 23, 2011
10.30	Employment Agreement, effective as of September 26, 2011, by and between the Registrant and Noah D. Beerman.#	8-K	—	10.30	September 26, 2011
10.32	Terms of Agreement, effective as of December 22, 2011, by and among the Registrant, Ovamed GmbH and Dr. Falk Pharma GmbH.	8-K	—	10.32	December 22, 2011

10.33	Amendment No. 1 to Employment Agreement, effective as of December 19, 2011, by and between the Registrant and Bobby W. Sandage, Jr., Ph.D.#	8-K	—	10.33	December 22, 2011
10.34	Side Agreement, effective as of November 15, 2011, by and between the University of Iowa Research Foundation, Ovamed GmbH and the Registrant.	8-K	—	10.34	December 22, 2011
10.35	Employment Agreement, made and entered into on February 21, 2012, by and between the Registrant and Lucy Lu, M.D.#	8-K	—	10.35	February 23, 2012
10.36	Collaboration Agreement, dated as of March 20, 2012, between the Registrant, Ovamed GmbH and Dr. Falk Pharma GmbH.†	8-K	—	10.36	March 23, 2012
10.37	Employment Agreement, made and entered into as of April 19, 2012, by and between the Registrant and Karin Hehenberger, M.D. and Ph.D.#	8-K	—	10.37	April 25, 2012
10.38	Amendment No. 2 to License Agreement, effective as of May 16, 2012, by and between the Registrant and UCL Business PLC.	8-K	—	10.38	May 25, 2012
10.39	Loan and Security Agreement, dated as of August 28, 2012, by and between the Registrant and Hercules Technology Growth Capital, Inc.	8-K	—	10.39	August 29, 2012
10.40	At Market Issuance Sales Agreement, dated as of October 5, 2012, by and between the Registrant and MLV & Co. LLC.	8-K	—	1.1	October 5, 2012
10.41	Second Amendment and Agreement, dated as of December 21, 2012, by and between the Registrant and Ovamed GmbH.†	10-K	—	10.41	March 18, 2013
10.42	Separation and Release Agreement and Consulting Agreement, dated as of December 28, 2012, by and between the Registrant and Glenn L. Cooper, M.D.#	10-K	—	10.42	March 18, 2013
10.43	Second Amendment to Employment Agreement, dated as of December 28, 2012, by and between the Registrant and Bobby W. Sandage, Jr.#	10-K	—	10.43	March 18, 2013
10.44	Employment Agreement, dated as of January 7, 2013 and effective as of December 28, 2012, by and between the Registrant and Harlan F. Weisman, M.D.#	10-K	—	10.44	March 18, 2013
10.45	Commercial Lease Agreement, effective March 1, 2013, by and between the Registrant and TSO Laboratories, Inc., as assigned to the Registrant on December 21, 2012.†	10-K	—	10.45	March 18, 2013

10.46	At Market Issuance Sales Agreement, dated April 29, 2013, between the Registrant and MLV & Co. LLC.	8-K	—	10.46	April, 29, 2013
10.47	Research Agreement, dated February 22, 2013, by and between the Registrant and Freie Universitat Berlin.†	10-Q	—	10.47	May 9, 2013
10.48	License and Sublicense Agreement, dated February 22, 2013, by and between the Registrant and Ovamed GmbH.†	10-Q	—	10.48	May 9, 2013
10.49	Coronado Biosciences, Inc. 2013 Stock Incentive Plan.#	8-K	—	10.49	June 21, 2013
10.50	Amendment No. 1 to At Market Issuance Sales Agreement, dated July 12, 2013, between the Registrant and MLV & Co. LLC.	S-3	333-189935	10.50	July 12, 2013
10.51	Amendment to Employment Agreement, dated April 19, 2013 by and between the Registrant and Dr. Karin Hehenberger, M.D., Ph.D.#	8-K	—	10.51	August 5, 2013
10.52	Executive Employment Agreement, dated November 5, 2013 by and between the Registrant and Kevin Horgan, M.D.#	8-K	—	10.52	November 6, 2013
10.53	Promissory Note issued by Registrant to Israel Discount Bank of New York, dated February 13, 2014.	8-K	—	10.53	February 18, 2014
10.54	Assignment and Pledge of Money Market Account dated February 13, 2014 in favor of Israel Bank of New York.	8-K	—	10.53	February 18, 2014
10.55	Restricted Stock Issuance Agreement, dated as of February 20, 2014, by and between the Registrant and Michael S. Weiss.	8-K/A	—	10.55	February 26, 2014
10.56	Shareholders' Agreement, dated as of February 20, 2014, by and among certain shareholders of the Registrant named therein.	8-K/A	—	10.56	February 26, 2014
10.57	Restricted Stock Issuance Agreement, dated as of December 19, 2013, by and between the Registrant and Michael S. Weiss.	10-K	—	10.57	March 14, 2014
10.58	Restricted Stock Issuance Agreement, dated as of December 19, 2013, by and between the Registrant and Lindsay A. Rosenwald, MD.	10-K	—	10.58	March 14, 2014
10.59	Confidential Separation and Release Agreement, dated as of December 22, 2013, by and between the Registrant and Harlan F. Weisman, MD.#	10-K	—	10.59	March 14, 2014
10.60	Form of Coronado Biosciences, Inc. 2013 Stock Incentive Plan Award Agreement (2013 Stock Incentive Plan).#	S-8	333-194588	10.60	March 14, 2014
10.61	Form of Subscription Agreement.	8-K	—	10.61	November 10, 2014

10.62	Note Purchase Agreement, dated February 27, 2015, by and between the Registrant and NSC BIOTECH VENTURE FUND I LLC.	8-K	—	10.62	March 5, 2015
10.63	Promissory Note issued by the Registrant to NSC BIOTECH VENTURE FUND I LLC, dated February 27, 2015.	8-K	—	10.63	March 5, 2015
10.64	Form of SubCo Securities Purchase Agreement.	8-K	—	10.64	March 5, 2015
10.65	Form of SubCo Warrant.	8-K	—	10.65	March 5, 2015
10.66	Form of SubCo Promissory Note.	8-K	—	10.66	March 5, 2015
14.1	Code of Ethics of Registrant applicable to Directors, Officers and Employees.	S-1	333-177041	14.1	September 28, 2011
16.1	Letter from PricewaterhouseCoopers LLP to the Securities and Exchange Commission dated April 7, 2014.	8-K	—	16.1	April 7, 2014
21.1	Subsidiaries of the Registrant.	—	—	—	Filed herewith
23.1	Consent Independent Registered Public Accounting Firm.	—	—	—	Filed herewith
23.2	Consent Independent Registered Public Accounting Firm.	—	—	—	Filed herewith
24.1	Power of Attorney (included on the signature page of this Form 10-K).	—	—	—	Filed herewith
31.1	Certification of Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.1	Certification of the Chairman, President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
101.INS	XBRL Instance Document.	—	—	—	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document.	—	—	—	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Filed herewith

101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Filed herewith

Management contract or compensatory plan.

† The registrant has received confidential treatment with respect to portions of this exhibit. Those portions have been omitted from the exhibit and filed separately with the U.S. Securities and Exchange Commission.

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Coronado Biosciences, Inc.

We have audited the accompanying consolidated balance sheet of Coronado Biosciences, Inc. and its subsidiaries (the "Company") as of December 31, 2014, and the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2014. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Coronado Biosciences, Inc. and its subsidiaries as of December 31, 2014, and the consolidated results of their operations and their cash flows for the year ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Coronado Bioscience Inc. and subsidiaries' internal control over financial reporting as of December 31, 2014, based on criteria established in the 2013 *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
March 16, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Coronado Biosciences, Inc.

We have audited Coronado Biosciences, Inc. and subsidiaries (the "Company") internal control over financial reporting as of December 31, 2014, based on criteria established in the 2013 *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Coronado Biosciences, Inc. and its subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in the 2013 *Internal Control - Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Coronado Biosciences, Inc. and its subsidiaries as of December 31, 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2014, and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
March 16, 2015

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Coronado Biosciences, Inc.

In our opinion, the consolidated balance sheet as of December 31, 2013 and the related consolidated statements of operations, of changes in convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of two years in the period ended December 31, 2013 present fairly, in all material respects, the financial position of Coronado Biosciences, Inc. and its subsidiaries (the "Company") at December 31, 2013, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/PricewaterhouseCoopers LLP

Boston, MA
March 14, 2014

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	December 31, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 49,759	$ 99,521
Marketable securities (Note 3)	20,002	—
Prepaid expenses and other current assets	702	510
Total current assets	70,463	100,031
Property & equipment, net	52	447
Restricted cash	14,586	—
Long-term investments, at fair value (Note 9)	4,160	—
Other assets	70	104
Total Assets	$ 89,331	$ 100,582
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 366	$ 468
Interest payable	28	109
Accrued expenses	3,683	4,430
Current portion of note payable	—	6,203
Total current liabilities	4,077	11,210
Note payable	14,009	7,017
Other long-term liabilities	722	1,077
Total Liabilities	18,808	19,304
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Convertible Preferred stock, $.001 par value, 129,767 Series C shares authorized, 0 shares issued and outstanding as of December 31, 2014 and 2013, respectively	—	—
Common Stock, $.001 par value, 100,000,000 shares authorized, 46,494,034 and 39,652,950 shares issued and outstanding as of December 31, 2014 and 2013, respectively	46	40
Additional paid-in capital	212,205	202,580
Accumulated deficit	(141,728)	(121,342)
Total Stockholders' Equity	70,523	81,278
Total Liabilities and Stockholders' Equity	$ 89,331	$ 100,582

The accompanying notes are an integral part of these consolidated financial statements.

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
($ in thousands except for share and per share amounts)

	For the Year Ended December 31,		
	2014	2013	2012
Operating expenses:			
Research and development	$ 10,239	$ 25,682	$ 17,468
General and administrative	10,413	10,098	8,665
In-process research and development	—	—	1,043
Loss from operations	(20,652)	(35,780)	(27,176)
Interest income	662	545	236
Interest expense	(1,338)	(1,923)	(670)
Change in fair value of investments	942	—	—
Net loss	$ (20,386)	$ (37,158)	$ (27,610)
Basic and diluted net loss per common share	$ (0.56)	$ (1.22)	$ (1.27)
Weighted average common shares outstanding—basic and diluted	36,323,596	30,429,743	21,654,984

The accompanying notes are an integral part of these consolidated financial statements.

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
($ in thousands except for share amounts)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balances at December 31, 2011	18,604,245	19	75,687	(56,574)	19,132
Issuance of Common Stock for cash	5,750,000	5	28,745	—	28,750
Costs related to issuance of Common Stock	—	—	(2,305)	—	(2,305)
Exercise of warrants	21,504	—	—	—	—
Issuance of Common Stock under ESPP	21,644	—	87	—	87
Issuance of Common Stock for At the Market Offering	3,361	—	19	—	19
Costs related to the issuance of Common stock for At the Market Offering	—	—	(1)	—	(1)
Stock-based compensation expense	—	—	3,961	—	3,961
Net loss	—	—	—	(27,610)	(27,610)
Balances at December 31, 2012	24,400,754	24	106,193	(84,184)	22,033
Exercise of stock options	550,157	1	969	—	970
Exercise of warrants	157,355	1	—	—	1
Issuance of Common Stock under ESPP	27,570	—	92	—	92
Issuance of Common Stock for At the Market Offering	10,558,422	10	91,327	—	91,337
Costs related to the issuance of Common stock for At the Market Offering	—	—	(1,899)	—	(1,899)
Issuance of Restricted Stock	3,958,692	4	(4)	—	—
Stock-based compensation expense	—	—	5,902	—	5,902
Net loss	—	—	—	(37,158)	(37,158)
Balances at December 31, 2013	39,652,950	$ 40	$ 202,580	$ (121,342)	$ 81,278
Exercise of stock options	323,412	—	596	—	596
Issuance of Common Stock related to subscription	2,175,000	2	3,500	—	3,502
Issuance of Common Stock under ESPP	13,980	—	19	—	19
Common Stock issuance costs	—	—	(32)	—	(32)
Issuance of Restricted Stock	4,328,692	4	(4)	—	—
Stock-based compensation expense	—	—	5,546	—	5,546
Net loss	—	—	—	(20,386)	(20,386)
Balances at December 31, 2014	46,494,034	$ 46	$ 212,205	$ (141,728)	$ 70,523

The accompanying notes are an integral part of these consolidated financial statements.

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
($ in thousands)

	For the Year Ended December 31,		
	2014	2013	2012
Cash flows from operating activities:			
Net loss	$ (20,386)	$ (37,158)	$ (27,610)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	5,546	5,902	3,638
Acquired in-process research and development	—	—	1,043
Noncash interest expense	634	536	130
Depreciation expense	23	17	3
Asset impairment	722	—	—
Change in fair value of investments	(942)	—	—
Changes in operating assets and liabilities:			
Prepaid, other current assets and short-term investment	(139)	(117)	(238)
Interest payable—related parties	—	—	(19)
Interest payable	(81)	(10)	119
Accounts payable and accrued expenses	(849)	1,184	(260)
End of term charge associated with Hercules Note	(398)	—	—
Other	(464)	—	—
Net cash used in operating activities	(16,334)	(29,646)	(23,194)
Cash flows from investing activities:			
Purchase of property and equipment	—	(40)	(54)
Purchase of investments, short-term	(346)	—	—
Purchase of investments, long-term	(2,925)	—	—
Deposit for leasehold improvements	—	(148)	(225)
Purchase of marketable securities, short-term	(20,002)	—	—
Net cash used in investing activities	(23,273)	(188)	(279)
Cash flows from financing activities:			
Payment of PCP notes payable—TSO asset purchase	—	—	(750)
Proceeds from issuance of Common Stock	4,117	92,399	28,855
Payment of costs related to the issuance of Common Stock	(32)	(1,898)	(2,305)
Payment of Hercules Note	(13,654)	(1,345)	—
Proceeds from issuance of Hercules Note	—	—	15,000
Proceeds from IDB Note	14,009		
Payment of debt issue costs associated with Hercules Note	—	—	(288)
Payment of debt issue costs associated with IDB Note	(9)	—	—
Transfer of restricted cash	(14,586)	—	—
Net cash (used in)/provided by financing activities	(10,155)	89,156	40,512
(Decrease)/Increase in cash and cash equivalents	(49,762)	59,322	17,039
Cash and cash equivalents—beginning of period	99,521	40,199	23,160
Cash and cash equivalents—end of period	$ 49,759	$ 99,521	$ 40,199

The accompanying notes are an integral part of these consolidated financial statements.

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
($ in thousands)

	For the Year Ended December 31,		
	2014	2013	2012
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 785	$ 1,387	$ 421
Supplemental disclosure of non-cash financing and investing activities:			
Issuance of Warrant related to Hercules Note	$ —	$ —	$ 323
Issuance of Restricted Stock	$ 4	$ 4	$ —

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Description of Business

Coronado Biosciences, Inc. (the "Company"), incorporated in Delaware on June 28, 2006, is a biopharmaceutical company involved in the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer, namely CNDO-201 or *Trichuris suis* ova ("TSO") and CNDO-109.

As part of the Company's growth strategy it has commenced and will continue to leverage its substantial biopharmaceutical business, financial and drug development expertise to invest in the acquisition, development and commercialization of novel pharmaceutical and other biomedical products. The Company is employing a variety of approaches and corporate structures to acquire rights to or finance a diverse portfolio of innovative pharmaceutical and biotechnology products, technologies and companies. These may include licensing, partnerships, joint ventures, direct financings and private or public spin-outs. As the Company continues to seek to acquire and advance investment opportunities with high growth potential, it is also exploring strategic options to realize value from our existing product candidates CNDO-201 and CNDO-109 clinical programs.

As of December 31, 2014, the Company has several subsidiaries: Innmune Limited, Coronado SO Co. ("Coronado SO"), Inc., Cyprium Inc., Altamira Bio Inc. (formerly TSO Development Corporation, Inc.), Journey Medical Corporation ("JMC") and CB Securities Corporation.

Recent 2014 Developments

On March 17, 2014, the Company made a $250,000 investment in a third party medical device company developing a laser device to treat migraine headaches. The investment represents a 35% ownership position in the company. The Company elected the fair value option and recorded this investment in long-term investment, at fair value in its Consolidated Balance Sheets as of December 31, 2014. (See Note 9).

Also on March 17, 2014, the Company provided a $50,000 bridge loan to a third party emerging specialty pharmaceutical company developing, marketing and distributing Epilepsy drugs. The bridge loan was due on June 16, 2014, accrued interest at a rate of 8% and was secured by the third party's assets. As of December 31, 2014, the bridge loan remained outstanding and the Company believes the loan is collectable since the assets securing the loan are believed to be worth more than the carrying amount of the loan. The Company recorded this bridge loan in other current assets in its Consolidated Balance Sheets as of December 31, 2014.

On April 18, 2014, the Company paid $243,000 to acquire an option to purchase ("Option") the exclusive rights to a pharmaceutical product from a third party and on August 12, 2014, the Company paid $50,000 to extend the Option for a total purchase price of $293,000. On September 30, 2014, the Option expired and the Company chose not to exercise the Option. Therefore, in connection with the expiration of the Option, the Company realized a loss of $293,000 which is recorded in change in fair value of short-term investment in the Consolidated Statements of Operations during the year ended December 31, 2014. (See Note 9).

In September 2014, the Company formed a blank check company incorporated in the Cayman Islands, CB Pharma Acquisition Corp. ("CB Pharma"), for the purpose of entering into a business combination with one or more businesses or entities, with a current focus in the specialty pharmaceuticals and generic drug industries, among other. Upon the formation of CB Pharma, the Company purchased 1.1 million insider shares of CB Pharma for $25,000, net of repurchase for 100,000 shares, since the over allotment option was not fully exercised. In December 2014, CB Pharma closed its initial public offering ("IPO"), including an over-allotment exercise, and a private placement raising net proceeds of $42.9 million, which proceeds are held in a trust account pending closing of a business combination. In conjunction with the IPO, the Company purchased 265,000 units of CB Pharma at $10.00 per unit for an aggregate purchase price of $2.7 million in a private placement. Each unit purchased includes the right to one-tenth of an ordinary share upon consummation of an initial business combination and a warrant exercisable for one-half an ordinary share to be exercised at $11.50 per share. The warrants are non-redeemable, and may be exercised the later of the completion of an initial business combination or 12 months following the prospectus date of December 12, 2014. None of the shares the Company purchased have liquidation rights. At December 31, 2014, the Company's investment in CB Pharma represented approximately 23% ownership in CB Pharma. The Company elected the fair value option to record this long-term investment and recorded a change in fair value of the investment of $1.2 million, for a total fair-value of $3.9 million as of December 31, 2014. The change in fair value was recorded in the Consolidated Statement of Operations as of December 31, 2014. (See Note 9).

In October 2014, the Company commenced operations of JMC. JMC is a wholly owned subsidiary that will acquire and license dermatology products for acne, steroid responsive dermatoses, pigmentation and antifungals for promotion to dermatologists and pediatricians. JMC is headquartered in Scottsdale, AZ and as of December 31, 2014, it had four full-time employees.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The Company's consolidated financial statements include the accounts of the Company and the accounts of the Company's subsidiaries: Innmune Limited, Coronado SO, Cyprium Inc., Altamira Bio Inc. (formerly TSO Development Corporation, Inc.), JMC and CB Securities Corporation. All intercompany balances and transactions have been eliminated.

Use of Estimates

The Company's consolidated financial statements include certain amounts that are based on management's best estimates and judgments. The Company's significant estimates include, but are not limited to, useful lives assigned to long-lived assets, fair value of stock options and warrants, investments, accrued expenses, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from our estimates.

Restricted Cash

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of December 31, 2014, the Company has $14.6 million of restricted cash securing a note payable of $14.0 million (see Note 11) and a pledge to secure a letter of credit in connection with a new lease of $0.6 million (see Note 7).

Fair Value Measurement

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured at fair value on a recurring basis. Under the accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Certain of the Company's financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable, accrued expenses and other current liabilities. The carrying value of the amount owed to Ovamed upon the acquisition of certain manufacturing rights in December 2012 under the amendment to our sublicense agreement with Ovamed, is included in both current liabilities and long-term liabilities in the Consolidated Balance Sheets has been recorded at its net present value, which approximates its fair value. (See Note 6).

Segment Reporting

The Company operates as one segment, in which management uses one measure of profitability, and all of the Company's assets are located in the United States of America. The Company is managed and operated as one business. The Company does not operate separate lines of business or separate business entities with respect to any of its product candidates. Accordingly, the Company does not have separately reportable segments.

Concentration of Risk

The Company is currently completely dependent on third-party manufacturers for product supply. In particular, the Company currently relies exclusively on Ovamed to supply it with its requirements of TSO, which is produced by Ovamed in its facility in Germany. Ovamed is the sole supplier of this product, which it is currently producing at only one facility in Germany, where it has also produced product for third parties, including Falk. Ovamed also relies on certain other suppliers for materials and services. On February 27, 2015, Ovamed filed for insolvency in Germany, a process similar to U.S. bankruptcy. At this time, the Company is unable to assess the likelihood of Ovamed continuing operations or being able to supply TSO. Similarly, the Company currently relies on BioReliance Corporation, Progenitor Cell Therapy, WuXi AppTec and other third parties for its CNDO–109 product requirements. The Company's clinical development programs would be adversely affected by a significant interruption in obtaining clinical trial supplies.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2014 and cash at December 31, 2013 consisted of cash in one institution in the United States. Balances at this institution have exceeded Federal Deposit Insurance Corporation insured limits and U.S. government agency securities.

Marketable Securities

Marketable securities are classified as trading and are carried at fair value. Marketable securities at December 31, 2014 consist of a U.S. Treasury Bill and mutual fund balances which are valued at market prices.

Property and Equipment

Office equipment is recorded at cost and depreciated using the straight-line method over the estimated useful life of each asset. Leasehold improvements are amortized over the shorter of the estimated useful lives or the term of the respective leases.

Deferred Financing Costs

Financing costs incurred in connection with both the Promissory Note for $15.0 million between Israel Discount Bank and the Company (the "IDB Note") and the Hercules Technology Growth Capital, Inc. ("Hercules") note payable were deferred and are being amortized over the appropriate expected life based on the term of the note using the effective interest rate method. As of December 31, 2014 and 2013, the Company recorded deferred financing costs of $6,000 and $43,000, respectively, in other assets in the accompanying consolidated balance sheets. The remaining deferred financing cost related to the Hercules note was expensed in 2014 when the note was paid off.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. During the year ended December 31, 2014, in connection to the abandonment of its lease in Woburn, MA, the Company recorded an impairment loss of $0.4 million related to the write-off of its construction in progress long-lived asset. (See Note 7).

Investments at Fair Value

The Company elected the fair value option for its expired short-term investment of $0.3 million to acquire the Option, long-term investment of $0.2 million in a third-party company developing a laser device to treat migraine headaches, and its investment in CB Pharma of $2.7 million in December 2014. During December 2014, the Company's investment in CB Pharma increased by $1.2 million which resulted in a total fair value of $3.9 million as of December 31, 2014.

The Company has various processes and controls in place to ensure that fair value is reasonably estimated.

While the Company believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

The decision to elect the fair value option, which is irrevocable once elected, is determined on an instrument by instrument basis and applied to an entire instrument. The net gains or losses, if any, on an investment for which the fair value option has been elected are recognized as a change in fair value of financial instruments, net, in the Consolidated Statements of Operations.

Research and Development

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved. Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use.

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

Contingencies

The Company records accruals for contingencies and legal proceedings expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

If a loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material, would be disclosed.

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates. For stock-based compensation awards to non-employees, the Company remeasures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change.

The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit.

Comprehensive Loss

The Company's comprehensive loss is equal to its net loss for all periods presented.

Recently Adopted Accounting Standards

On February 18, 2015, the FASB issued ASU 2015-2, *Consolidation (Topic 820): Amendments to the Consolidation Analysis*. ASU 2015-2 provides a revised consolidation model for all reporting entities to use in evaluating whether they should consolidate certain legal entities. All legal entities will be subject to reevaluation under this revised consolidation model. The revised consolidation model, among other things, (i) modifies the evaluation of whether limited partnerships and similar legal entities are VIEs or voting interest entities, (ii) eliminates the presumption that a general partner should consolidate a limited partnership, and (iii) modifies the consolidation analysis of reporting entities that are involved with VIEs through fee arrangements and related party relationships. This guidance in ASU 2015-2 is effective for the Company beginning on January 1, 2016, however, early adoption is permitted. The Company is currently assessing the potential impact that this guidance will have on its consolidated financial statements.

In June 2014, the FASB issued Accounting Standard Update No. 2014-10, *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this update remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. A public entity is required to apply the amendments for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early adoption is permitted. An entity should apply the amendments retrospectively for all comparative periods presented. The Company elected to adopt the guidance in the second quarter of 2014. Adoption of this standard did not have a material impact on the Company's financial position, statement of operations, or statement of cash flows.

In August 2014, the FASB issued ASU 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15 provides guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. The amendments in ASU 2014-15 are effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company will adopt the methodologies prescribed by ASU 2014-15 by the date required, and does not anticipate that the adoption of ASU 2014-15 will have a material effect on its financial position or results of operations.

In June 2014, the FASB issued ASU 2014-12, Compensation-Stock Compensation (Topic 718). The ASU clarifies how entities should treat performance targets that can be achieved after the requisite service period of a share-based payment award. The accounting standard is effective for interim and annual periods beginning after December 15, 2015. The Company is currently in the process of evaluating the impact of the guidance on its financial position, results of operation, and cash flows.

3. Marketable Securities

Marketable securities, classified as trading, consist of the following:

	As of December 31, 2014			
($ in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair value
U.S. treasury bill	$ 19,998	$ —	$ —	$ 19,998
Mutual fund	4	—	—	4
	$ 20,002	$ —	$ —	$ 20,002

The contractual term to maturity of all marketable securities held by the Company as of December 31, 2014 is less than one year. The Company did not hold any marketable securities as of December 31, 2013.

4. Net Loss Per Common Share

The Company calculates loss per share using the two-class method, which is an earnings allocation formula that determines earnings per share for Common Stock and participating securities, if any, according to dividends declared and non-forfeitable participation rights in undistributed earnings. Under this method, all earnings (distributed and undistributed) are allocated to Common Stock and participating securities, if any, based on their respective rights to receive dividends. Holders of restricted Common Stock were entitled to all cash dividends, when and if declared, and such dividends are non-forfeitable. The participating securities do not have a contractual obligation to share in any losses of the Company. As a result, net losses are not allocated to the participating securities for any periods presented.

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of Common Stock outstanding during the period, without consideration for Common Stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of Common Stock and Common Stock equivalents outstanding for the period.

A calculation of basic and diluted net loss per share follows:

	For the year ended December 31,		
	2014	2013	2012
($ in thousands except share and per share amounts)			
Historical net loss per share:			
Numerator			
Net loss	$ (20,386)	$ (37,158)	$ (27,610)
Denominator			
Weighted-average common shares outstanding— Denominator for basic and diluted net loss per share	36,323,596	30,429,743	21,654,984
Basic and diluted net loss per share attributed to common stockholders	$ (0.56)	$ (1.22)	$ (1.27)

Included in Common Stock issued and outstanding as of December 31, 2014 are 8,287,384 shares of unvested restricted stock, which is excluded from the average weighted Common Stock outstanding since its effect would be dilutive.

The Company's potential dilutive securities which consist of unvested stock restricted stock, options, and warrants have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average Common Stock outstanding used to calculate both basic and diluted net loss per share is the same.

The following shares of potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as the effect of including such securities would be antidilutive:

	For the year ended December 31,		
	2014	2013	2012
Warrants to purchase Common Stock	693,636	1,012,977	1,091,558
Options to purchase Common Stock	2,276,813	3,936,199	2,279,603
Unvested Restricted Stock	6,087,717	140,995	—
	9,058,166	5,090,171	3,371,161

5. Property and Equipment

Property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	As of December 31, 2014	2013
Construction in progress	N/A	$ —	$ 373
Computer equipment	3	13	13
Furniture & fixtures	5	69	69
Leasehold improvements	5	12	12
Total property and equipment		94	467
Less: Accumulated depreciation		(42)	(20)
Property and equipment, net		$ 52	$ 447

During the year ended December 31, 2014, in relation to the abandonment of its Woburn, MA manufacturing facility, the Company recorded $0.4 million of impairment loss related to the write-off of its construction in progress long-lived asset. (See Note 7).

Depreciation expense for the years ended December 31, 2014, 2013, and 2012 was $23,000, $17,000, and $3,000, respectively, and was recorded in both research and development expense and general and administrative expense in the consolidated statements of operations.

Depreciation expense for the years ended December 31, 2013, 2012, and 2011 and the period from inception to December 31, 2013 was $ 17 ,000, $ 3 ,000, $ 22 ,000 and $ 61 ,000 which includes $ 41 ,000 of computer equipment write-offs, respectively, and was recorded in both research and development expense and general and administrative expense in the consolidated statements of operations

6. Accrued Liabilities and other Long-Term Liabilities

Accrued expenses and other long-term liabilities consisted of the following:

	As of December 31,	
($ in thousands)	2014	2013
Accrued expenses:		
Salaries, bonuses and employee benefits	$ 598	$ 450
Severance (Note 16)	38	1,502
Professional fees	837	351
Research and development expenses	832	1,245
State franchise taxes	—	190
Ovamed manufacturing rights – short-term component (Note 15)	1,000	500
Short-term lease impairment charge	165	—
Other	213	192
Total accrued expenses	$ 3,683	$ 4,430
Other long-term liabilities:		
Hercules Note end of term charge (Note 11)	—	398
Ovamed manufacturing rights – long-term component (Note 15)	334	679
Long-term lease impairment charge	268	—
Deferred rent	120	—
Total other long-term liabilities	$ 722	$ 1,077

In December 2012, the Company acquired certain manufacturing rights from Ovamed and agreed to pay an aggregate of $1.5 million, in three installments of $500,000 on December 12, 2014, 2015 and 2016, respectively. As of December 31, 2014, the Company had not paid any of the amount due to Ovamed. The accrual is recorded at present value on the Company's Consolidated Balance Sheets as a current accrued expense of $1.0 million and as a long-term liability of $334,000 as of December 31, 2014. This obligation was recorded at its estimated net present value; accretion of the obligation was $154,000 and $136,000 for the years ended December 31, 2014 and 2013, respectively, and is recorded as interest expense.

7. Commitments and Contingencies

Operating Lease Obligations

In November 2014, JMC entered into a two-year lease for 2,295 square feet of office space in Scottsdale, AZ at an average annual rent of approximately $39,000. JMC took occupancy of this space in November 2014.

On October 3, 2014, the Company entered into a 15-year lease for office space in New York, NY at an average annual rent of $2.7 million. Also, on October 3, 2014, the Company entered into Desk Space Agreements with two related parties: Opus Point Partners Management, LLC ("OPPM") and TG Therapeutics, Inc. ("TGTX"), to occupy 20% and 40%, respectively, of the New York, NY office space that requires them to pay their share of the average annual rent of $0.5 million and $1.1 million, respectively. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. Additionally, the Company has reserved the right to execute desk space agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by the Company. The Company does not expect to take possession of the space until early 2016 and lease expense will commence upon occupancy of the space. The lease was executed to further the Company's business strategy, which includes forming additional subsidiaries and/or affiliate companies. The lease is subject to early termination by the Company, or in circumstances including events of default, the landlord, and includes a five-year extension option in favor of the Company. At December 31, 2014, the Company paid $199,000 of prepaid rent and under the Desk Space Agreement, was reimbursed by OPPM and TGTX for their prorated share of this prepayment.

In April 2013, the Company entered into a three-year lease for approximately 1,500 square feet of office space in New York, NY at an average annual rent of approximately $122,000. The Company commenced occupancy of this space in May 2013. In March 2014, the Company made the decision to close the New York, NY office and commenced marketing the facility for sub-lease. In April 2014, the Company entered into a sub-lease arrangement for this New York, NY office for the remaining term of the lease, and in December 2014, the sub-tenant returned the space. The company continues to seek a sub-tenant.

Pursuant to the Second Amendment and Agreement, dated as of December 21, 2012, by and between the Company and Ovamed, (the "Manufacturing Agreement") (see Note 15), in December 2012, the Company entered into an Assignment and Assumption of Lease ("Assignment") with TSO Laboratories, Inc., a wholly owned subsidiary of Ovamed, for approximately 8,700 square feet in Woburn, MA for the purpose of establishing a manufacturing facility. Total rent expense for the five-year lease term was approximately $590,000 at an average annual rate of $118,000. As of December 31, 2013, the Company had spent $373,000 in leasehold improvement costs associated with this lease. In March 2014, the Company abandoned its plans to build out the Woburn, MA manufacturing facility. As a result, the Company commenced marketing the facility for sub-lease. As of December 31, 2014, the space has not been sublet, and the company continues to seek a sub-tenant.

During the year ended December 31, 2014, the Company recognized impairment expense as a result of its decision to abandon the buildout of a manufacturing facility of approximately $0.7 million, which is included in research and development expenses. Expense related to the year ended December 31, 2014 was composed of $0.7 million related to the decision to delay manufacturing of TSO in the Woburn, MA facility, which included future rent payments of $0.3 million through the lease termination date of February 2018, offset by $0.1 million of rental income from a probable sublease, and $0.4 million related to the write-down, to its estimated net realizable value, of its long-lived assets. The Company also recognized $0.1 million in expense related to a sub-lease for the Company's New York, NY office space effective May 1, 2014 through the termination of the lease in May 2016.

In July 2012, the Company entered into a five-year lease for approximately 3,200 square feet of office space in Burlington, MA at an average annual rent of approximately $94,000. The Company took occupancy of this space in October 2012. In January 2015, the Company exercised the early termination option, whereby reducing the term of this lease to three years. The Company paid $82,000 to exercise this option in January 2015.

Total future minimum lease payments under these leases are:

($ in thousands)		
2015	$	461
2016		2,633
2017		2,562
2018		2,490
2019		2,504
Beyond		30,883
Total minimum lease payments	$	41,533

The Company recognizes rent expense on a straight-line basis over the non-cancellable lease term. Rent expense for the years ended December 31, 2014, 2013 and 2012 was $354,000, $284,000, and $93,000, respectively.

Indemnification

In accordance with its certificate of incorporation, bylaws and indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance to address such claims. Pursuant to agreements with clinical trial sites, the Company provides indemnification to such sites in certain conditions.

Legal Proceedings

In the ordinary course of business, the Company and its subsidiaries may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers, partners and/or third parties (including tort claims for personal injury arising from clinical trials of the Company's product candidates and property damage) alleging deficiencies in performance, breach of contract, etc., and seeking resulting alleged damages. No claims have been brought against the Company and its subsidiaries.

8. Employee Benefit Plan

On January 1, 2008, the Company adopted a defined contribution 401(k) plan which allows employees to contribute up to a percentage of their compensation, subject to IRS limitations and provides for a discretionary Company match up to a maximum of 4% of employee compensation. For the years ended December 31, 2014, 2013 and 2012, the Company paid a matching contribution of $83,000, $107,000 and $85,000, respectively.

9. Fair Value Measurement

From time to time, the Company invests in marketable securities, which are classified as trading securities and are stated at fair value as determined by quoted market prices. As of December 31, 2014, the Company held $20.0 million in marketable securities, which primarily consisted of a U.S. treasury bill. As of December 31, 2013, the Company did not hold any marketable securities.

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable, accrued expenses and other current liabilities. The carrying value of the accrued Ovamed Manufacturing Agreement rights license included in both current liabilities and long-term liabilities in the consolidated balance sheets has been recorded at its net present value, which approximates its fair value.

The estimated fair value of the Hercules note payable at December 31, 2013, computed using the effective interest rate method, was $13.7 million. The effective interest rate considers the fair value of the warrant issued in connection with the loan, loan issuance costs and the deferred charge. The fair value measurement utilizes inputs that are categorized as Level 3.

On March 17, 2014, the Company invested $250,000 for a 35% ownership position in a third-party company developing a laser device to treat migraine headaches. The Company elected the fair value option for recording this investment. In conjunction with this investment, the Company entered into a Purchase Agreement with the third-party company, in which the Company received 13,409,962 Class A Preferred Units, representing 83% of a total 16,091,954 Class A Preferred Units.

On April 18, 2014, the Company paid $243,000 for the Option to purchase the exclusive rights to a Phase 2, topical product, 1UO, a third party and paid an additional $50,000 in August 2014 to extend the term of the Option for a total purchase price of $293,000. On September 30, 2014, the Company recognized a loss of $293,000 in connection with the expiration of the Option. As of December 31, 2014 this loss was reflected in the Consolidated Statement of Operations.

In September 2014, the Company formed CB Pharma, a blank check company and received 1.1 million insider shares of CB Pharma in exchange for $25,000. In December 2014, CB Pharma closed its IPO, including an over-allotment exercise, and a private placement raising net proceeds of $42.9 million. In connection with the IPO, in a private placement, the Company purchased 265,000 units of CB Pharma at $10.00 per unit. Each unit included one ordinary share, one right to receive one-tenth of a ordinary share upon consummation of a business combination and a warrant exercisable for one-half of an ordinary share at $11.50 per share upon the later of a business combination or twelve months from December 12, 2014 and expiring in five years, for an aggregate purchase price of $2.7 million. None of the ordinary shares or units purchased by the Company have liquidation rights. The Company valued their investment in CB Pharma in accordance with ASC Topic 820, *Fair Value Measurements and Disclosures*, and estimated the fair value to be $3.9 million. The value of these ordinary shares and rights were based on the trading prices in January 2015, upon the commencement of CB Pharma's instruments trading separately. Since the insider shares are restricted through a specified period following a business combination, the "*Ghaidarov Model*" was utilized to estimate a discount for lack of marketability with the following assumptions: risk free rate of return of 0.1%, the restriction period of approximately one year from a business combination, volatility of 9.3%, and no dividend rate; yielding an underlying value of $2.93 per ordinary share for the insider shares and $2.99 per ordinary share for the private placement units. The rights and warrants were valued utilizing a binomial-lattice model which assumes a volatility of 20.7%, a risk free rate of return of 1.68% and a strike price of $11.50 per share, and applied a probability factor (implied likelihood of a successful business combination occurring within 18 months from the IPO date) arriving at an estimated value of $0.18 for each warrant and $0.30 for each right. Based upon the valuation, the Company recorded a change in fair-value of investment of $1.2 million; increasing the fair value of the investment to $3.9 million as of December 31, 2014. As of December 31, 2014, CB Pharma had net assets, including ordinary shares subject to possible redemption, of approximately $38.0 million. Operations since inception have been insignificant. The Company has a working capital commitment of up to $0.5 million to fund CB Pharma Operations. As of December 31, 2014 the fair value of this commitment was insignificant.

The value of the Company's investment in the third party developing a laser treatment for migraine headaches and the Option were determined based on a valuation which takes into consideration, when applicable, cash received, cost of the investment, market participant inputs, estimated cash flows based on entity specific criteria, purchase multiples paid in other comparable third-party transactions, market conditions, liquidity, operating results and other qualitative and quantitative factors. The values at which the Company's investments are carried on its books are adjusted to estimated fair value at the end of each quarter taking into account general economic and stock market conditions and those characteristics specific to the underlying investments. Based upon these inputs at December 31, 2014, the fair values approximated cost.

The following table classifies into the fair value hierarchy, financial instruments measured at fair value on a recurring basis in the accompanying Consolidated Balance Sheets as of December 31, 2014; at December 31, 2013, the Company had no investments at fair value:

	Fair Value Measurement as of December 31, 2014			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets				
Marketable securities:				
U.S. treasury bills	$ 19,998	$ —	$ —	$ 19,998
Mutual funds	4	—	—	4
Total marketable securities	20,002	—	—	20,002
Long-Term Investments, at fair value (1)	—	—	4,160	4,160
Total	$ 20,002	$ —	$ 4,160	$ 24,162

The table below provides a rollforward of the changes in fair value of Level 3 financial instruments for the year ended December 31, 2014:

	Fair Value of Investments			
	Short-term	Long-term		
($ in thousands)	Other	Other	CB Pharma	Total
Balance at December 31, 2013	$ —	$ —	$ —	$ —
Purchases	293	250	2,675	3,218
Change in fair value of investment	(293)	—	1,235	942
Balance at December 31, 2014	$ —	$ 250	$ 3,910	$ 4,160

10. Related Party Transactions

Other Related Parties

The Company's Chairman, President and Chief Executive Officer, individually and through certain trusts over which he has voting and dispositive control, beneficially owned approximately 12.4% and 14.1% of the Company's issued and outstanding Common Stock as of December 31, 2014 and 2013. The Company's Executive Vice Chairman, Strategic Development individually owns approximately 14.9% of the Company at December 31, 2014.

Related Party Service Agreement

On April 3, 2014, the Company entered into a Shared Services Agreement with OPPM in which the parties agreed to share a rented facility as well as costs for certain services, which they individually require for the operation of their respective entities. The Company's Chairman, President and Chief Executive Officer and the Company's Executive Vice President, Strategic Development, are both Co-Portfolio Managers and Partners of OPPM. The Company incurred expense of approximately $141,000 for the year ended December 31, 2014, no expense was incurred in 2013. The agreement can be terminated by either party with thirty days' notice.

Desk Space Agreement

On October 3, 2014 the Company entered into Desk Space Agreements with OPPM and TGTX, to occupy 20% and 40%, respectively, of their New York, NY office space in the first half of 2016. These agreements require OPPM and TGTX to pay their respective share of the average annual rent of $0.5 million and $1.1 million, respectively. These initial rent allocations will be adjusted periodically, for each party, based upon actual percentage of the office space occupied. Additionally, the Company has reserved the right to execute desk space agreements with other related and unrelated third parties and those arrangements will also affect the cost of the lease actually borne by the Company. The lease was executed by the Company to further the Company's business strategy, which includes forming additional subsidiaries and/or affiliate companies. The lease is subject to early termination by the Company, or in circumstances including events of default, by the landlord, and includes a five-year extension option in favor of the Company. In connection with the lease the Company paid $0.2 million representing prepaid rent for the first month. Both OPPM and TGTX reimbursed the Company for their respective share of the first months rent; representing $0.1 million, which was recorded in other liabilities in the Consolidated Balance Sheet as of December 31, 2014.

11. Debt

IDB Note

On February 13, 2014, the Company executed a promissory note in favor of IDB in the amount of $15.0 million (the "IDB Note"). The Company borrowed $14 million against this note and used it to repay its prior loan from Hercules. The Company may request revolving advances under the IDB Note in a minimum amount of $100,000 (or the remaining amount of the undrawn balance under the IDB Note if such amount is less than $100,000). All amounts advanced under the IDB Note are due in full at the earlier of: (i) February 13, 2016, or (ii) on the IDB's election following the occurrence and continuation of an event of default. The unpaid principal amount of each advance shall bear interest at a rate per annum equal to the rate payable on the Company's money market account plus a margin of 150 basis points. The interest rate at December 31, 2014 was 2.25%. The IDB Note contains various representations and warranties customary for financings of this type.

The obligations of the Company under the IDB Note are collateralized by a security interest in, a general lien upon, and a right of set-off against the Company's money market account of $ 15.0 million pursuant to the Assignment and Pledge of Money Market Account, dated as of February 13, 2014 (the "Pledge Agreement"). Pursuant to the Pledge Agreement, the Bank may, after the occurrence and continuation of an event of default under the IDB Note, recover from the money market account all amounts outstanding under the IDB Note. The Pledge Agreement contains various representations, warranties, and covenants customary for pledge agreements of this type.

The Company will default on the IDB Note if, among other things, it fails to pay outstanding principal or interest when due. Following the occurrence of an event of default under the IDB Note, the Bank may: (i) declare the entire outstanding principal balance of the IDB Note, together with all accrued interest and other sums due under the IDB Note, to be immediately due and payable; (ii) exercise its right of setoff against any money, funds, credits or other property of any nature in possession of, under control or custody of, or on deposit with the Bank; (iii) terminate the commitments of the Bank; and (iv) liquidate the money market account to reduce the Company's obligations to the Bank.

Hercules Debt Agreement

In August 2012, the Company entered into a Loan and Security Agreement (the "Loan Agreement") pursuant to which the Company issued a $15 million note (the "Hercules Note") and received net proceeds of $ 14.7 million. The loan bore interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 9.25% plus the sum of the prevailing prime rate minus 3.25%. The loan was to mature on March 1, 2016. The loan required interest-only payments for the initial 12 months and thereafter requires repayment of the principal balance with interest in 30 monthly installments. The Company had the option to extend the interest-only period for an additional six months, contingent upon the Company's achievement of certain clinical development milestones. In connection with the Loan Agreement, the Company granted first priority liens and the loan was collateralized by substantially all of the Company's assets (exclusive of intellectual property). The Loan Agreement also contains representations and warranties by the Company and Hercules and indemnification provisions in favor of Hercules and customary covenants (including limitations on other indebtedness, liens, acquisitions, investments and dividends, but no financial covenants), and events of default (including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of Hercules' security interest or in the collateral, and events relating to bankruptcy or insolvency). Pursuant to the Loan Agreement, Hercules had the right to participate, in an amount of up to $2,000,000, in subsequent private placements of our equity securities at the same terms and conditions, including price, as purchases by other investors. In connection with the Loan Agreement, the Company issued to Hercules a fully-vested, seven-year warrant (the "Warrant") to purchase 73,009 shares of its Common Stock at an exercise price of $5.65 per share and granted to Hercules certain "piggyback" registration rights with respect to the shares of Common Stock underlying the Warrant.

The fair value of the Warrant was calculated using the Black-Scholes option-pricing model with the following assumptions: volatility of 87.2%, an expected term equal to the contractual seven-year life of the Warrant, a risk-free interest rate of 1.1% and no dividend yield. The Company recorded the fair value of the Warrant of approximately $323,000 as equity and as a discount to the carrying value of the loan. Also, upon full repayment or maturity of the loan, Hercules is due a payment of 2.65% of the loan, or $398,000, which is recorded as a discount to the loan and as a long-term liability. Additionally, the Company incurred fees related to the Loan Agreement and reimbursed Hercules for costs incurred by them related to the loan aggregating $218,000 and which is reflected as a discount to the carrying value of the loan. The Company will amortize these loan discounts totaling $939,000 to interest expense over the term of the loan using the effective interest rate method, which approximates 12.3%. For the years ended December 31, 2014, 2013 and 2012, interest expense related to the Hercules loan was $845,000, $1,767,000 and $609,000, respectively, including $435,000, $381,000 and $123,000 related to accretion of the debt discount, respectively. At December 31, 2013, the current portion of the Hercules Note was $6,203,000 and noncurrent portion was $7,017,000 which was net of the debt discount of $434,000 was recorded on the Consolidated Balance Sheet.

On February 13, 2014, the Company repaid the Hercules Note in full. Early Payment of the Hercules Note was $14.0 million, consisting of principal of $13.2 million, end of term charge of $ 0.4 million, a prepayment fee of $0.3 million and interest of $0.1 million.

Interest Expense

Interest expense for the years ended December 31, 2014, 2013 and 2012 was $1.3 million, $1.9 million and $670,000, respectively. During the years ended December 31, 2014, 2013 and 2012, interest expense related to the Hercules Note was $845,000, $1.7 million and $609,000, respectively, including $435,000, $381,000 and $123,000 related to accretion of the debt discount, and $43,000, $20,000, and $6,600 related to the amortization of financing costs, respectively. For the year ended December 31, 2014, interest expense incurred on the IDB Note was $292,000, and $4,000 related to amortization of financing costs.

12. Equity

Common Stock

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 15,000,000 shares of $0.001 par value Preferred Stock (none of which is outstanding at December 31, 2014 and 2013) and 100,000,000 shares of $0.001 par value Common Stock.

The terms, rights, preference and privileges of the Common Stock are as follows:

Voting Rights

Each holder of Common Stock is entitled to one vote per share of Common Stock held on all matters submitted to a vote of the stockholders, including the election of directors. The Company's certificate of incorporation and bylaws do not provide for cumulative voting rights.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of the Company's outstanding shares of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Company's board of directors out of legally available funds.

Liquidation

In the event of the Company's 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 the Company's debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of Preferred Stock.

Rights and Preference

Holders of the Company's Common Stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our 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 the Company's preferred stock that are or may be issued.

Fully Paid and Nonassessable

All of the Company's outstanding shares of Common Stock are fully paid and nonassessable.

At Market Issuance Programs

In September 2012, the Company filed a shelf registration statement on Form S-3 (the "2012 Form S-3") pursuant to which it could sell up to a total of $75.0 million of its equity securities and, in October 2012, entered into an At Market Issuance Sales Agreement with MLV & Co LLC ("MLV") to issue and sell up to $30.0 million of shares of Common Stock under the 2012 Form S-3 (the "2012 ATM"). Upon completion of the 2012 ATM, in April 2013, the Company entered into a new At Market Issuance Sales Agreement with MLV whereby it could issue and sell up to $45.0 million of shares of Common Stock under the 2012 Form S-3 (the "2013 ATM").

In July 2013, the Company filed a shelf registration statement on Form S-3 (the "2013 Form S-3"), which was declared effective on August 19, 2013. The Company may sell up to a total of $200.0 million of its equity securities under the 2013 Form S-3. In connection with the 2013 Form S-3, the Company amended its 2013 ATM with MLV such that it may offer and sell additional shares of Common Stock having an aggregate offering price of up to $70.0 million from time to time under the 2013 Form S-3 (the "Amended 2013 ATM"). Pursuant to the terms of the ATMs with MLV, the Company will pay directly to MLV fees of up to 3% of the gross proceeds of the ATM then in effect. In the year ended December 31, 2013, the Company sold 10,558,422 shares of Common Stock under the ATMs and received net proceeds of $89.4 million. During the year ended December 31, 2014, the Company incurred approximately $32,000 of cost for comfort letters in connection with the 2013 ATM.

November 2014 Subscription Agreement

On November 6, 2014, the Company issued an aggregate of 2,175,000 shares of its Common Stock to its Chairman, President and Chief Executive Officer, its Executive Vice Chairman, Strategic Development, a member of its board of directors, and an investor unaffiliated with the Company. The Company's board of directors and Audit Committee approved the private placement which is exempt from registration under the Securities Act of 1933, as amended pursuant to Section 4(a)(2) thereof. The shares of Company Common Stock were sold at $1.61 per share, the closing price on November 6, 2014, and resulted in aggregate cash proceeds to the Company of approximately $3.5 million.

13. Warrants to Purchase Common Stock

Non-Employee Warrants

In 2013, the Company issued 78,710 shares of Common Stock pursuant to cashless exercises of 153,415 warrants to consultants for a weighted average exercise price of $5.00 per share.

In 2013, the Company issued 78,636 shares of Common Stock pursuant to the cashless exercise of 328,510 warrants at a weighted average exercise price of $5.45, and 340 shares of Common Stock for cash proceeds of $1,098.

For the year ended December 31, 2014, the Company did not issue any shares of Common Stock pursuant to the exercise of warrants. At December 31, 2014, the Company had outstanding warrants of 711,895.

14. Stock Plans and Stock-Based Compensation

The Company has three equity compensation plans, the Coronado Biosciences, Inc. 2007 Stock Incentive Plan (the "2007 Plan"), the Coronado Biosciences, Inc. 2013 Stock Incentive Plan, (the "2013 Plan") and the 2012 Employee Stock Purchase Plan (the "ESPP"). In 2013, the Company's board of directors adopted and stockholders approved the 2013 Plan authorizing the Company to grant up to 2,300,000 shares of Common Stock to eligible employees, directors and consultants in the form of stock options, stock appreciation rights, restricted stock awards, and restricted stock unit awards. In 2007, the Company's board of directors adopted and stockholders approved the 2007 Plan authorizing the Company to grant up to 6,000,000 shares of Common Stock to eligible employees, directors, and consultants in the form of restricted stock, stock options and other types of grants. The amount, terms, and exercisability provisions of grants under both the 2013 Plan and 2007 Plan are determined by the board of directors.

The purpose of the Company's equity compensation plans is to provide the Company with the flexibility to use shares, options or other awards as part of an overall compensation package of performance-based rewards to attract and retain qualified personnel. Such awards include, without limitation, options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. Vesting of awards may be based upon the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions. There were 2,300,000 shares of Common Stock reserved for issuance under the 2013 Plan and 6,000,000 shares of Common Stock reserved for issuance under the 2007 Plan, of which an aggregate of 7,043,280 were granted under both plans, net of cancellations, and 1,256,720 shares were available for issuance as of December 31, 2014.

Incentive and nonstatutory stock options are granted pursuant to option agreements adopted by the plan administrator. Options generally have 10-year contractual terms and vest in three equal annual installments commencing on the grant date.

The Company estimates the fair value of stock option grants using a Black-Scholes option pricing model. In applying this model, the Company uses the following assumptions:

- *Risk-Free Interest Rate:* The risk-free interest rate is based on the yields of United States Treasury securities with maturities similar to the expected term of the options for each option group.

- *Volatility:* As the Company has a limited trading history for its Common Stock, the expected stock price volatility for its Common Stock was estimated by incorporating two years of the Company's historical volatility and the average historical price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. The Company's historical volatility is weighted with that of the peer group and that combined historical volatility is weighted 80% with a 20% weighting of the Company's implied volatility, which is obtained from traded options of the Company's stock. The Company intends to continue to consistently apply this process using the same or similar public companies until it has sufficient historical information regarding the volatility of its Common Stock that is consistent with the expected life of the options. Should circumstances change such that the identified companies are no longer similar to the Company, more suitable companies whose share prices are publicly available would be utilized in the calculation.

- *Expected Term:* Due to the limited exercise history of the Company's stock options, the Company determined the expected term based on the Simplified Method under SAB 107 and the expected term for non-employees is the remaining contractual life for both options and warrants.

- *Expected Dividend Rate:* The Company has not paid and does not anticipate paying any cash dividends in the near future.

The fair value of each option award was estimated on the grant date using the Black-Scholes option-pricing model and expensed under the straight line method. The weighted-average grant date fair value per share relating to stock options granted during the years ended December 31, 2013 and 2012 was $3.77 and $5.74 respectively. There were no stock options issued during the year ended December 31, 2014. The following assumptions were used:

	2014	2013	2012
Exercise price	n/a	$1.71–$9.21	$4.75–$7.84
Expected stock price volatility	n/a	81.3%–112.7%	87.3%–114.3%
Risk free rate of interest	n/a	1.01%–3.04%	0.16%–2.23%
Expected life of options	n/a	6 years–10 years	2 years–10 years

The fair value for non-employee stock based awards are mark-to-market on each valuation date until vested using the Black-Scholes pricing model.

The following table summarizes the stock-based compensation expense from stock option, employee stock purchase programs and restricted Common Stock awards and warrants for the years ended December 31, 2014, 2013 and 2012

($ in thousands)	2014	2013	2012
Employee awards	$ 5,492	$ 4,867	$ 2,408
Non-employee awards	54	897	664
Non-employee warrants	—	138	566
Total compensation expense	$ 5,546	$ 5,902	$ 3,638

For the year ended December 31, 2014, 2013 and 2012, $1.1 million, $3.0 million and $1.5 million was included in research and development expenses and $4.4 million, $2.9 million and $2.1 million was included in general and administrative expenses, respectively.

The following table summarizes stock option activity:

	Outstanding Options			Weighted Average Remaining Contractual Life (in years)
($ in thousands except per share amounts)	Number of Shares	Weighted Average Exercise Price	Total Weighted Average Intrinsic Value	
Outstanding at December 31, 2013	3,117,777	$ 4.31	$ —	8.36
Options granted	—	$ —	—	
Options exercised	(323,412)	$ 1.84	193	
Options cancelled/forfeited	(630,000)	$ 4.28	—	
Outstanding at December 31, 2014	2,164,365	$ 4.69	$ —	7.38
Options vested and expected to vest	2,164,365	$ 4.69	$ —	7.38
Options vested and exercisable	1,731,032	$ 4.33	$ —	7.18

As of December 31, 2014, the Company had unrecognized stock-based compensation expense related to all unvested stock options of $1.2 million, which is expected to be recognized over the remaining weighted-average vesting period of 0.6 years.

During the years ended December 31, 2014 and 2013, exercises of stock options resulted in total proceeds of approximately $0.6 million and $1.0 million, respectively.

Restricted Stock

During 2013 and 2014, the Company granted restricted shares of its Common Stock to executives, employees and directors of the Company. The 2013 restricted stock awards vest based upon both the passage of time as well as certain pre-defined market conditions. The fair value of the restricted stock awards issued during 2014 of $11.6 million was estimated on the grant date using the Company's stock price on the date of grant. As the 2013 restricted stock awards included performance based vesting criteria, the fair value of those restricted stock awards of $7.6 million was estimated on the grant date using the Monte Carlo simulation model. Significant assumptions included a volatility of 114.2% based upon an expected 5 year life and a risk-free rate of return of 1.55% associated with five year Treasury Securities yields. The 2014 restricted stock awards vest upon both the passage of time as well as meeting certain performance criteria. Restricted stock awards are expensed under the straight line method over the vesting period.

Stock-based compensation expense from restricted stock awards for the year ended December 31, 2014 and 2013 was $4.0 million and $66,000, respectively. There was no stock-based compensation expense related to restricted stock awards for the year ended December 31, 2012.

The following table summarizes restricted stock activity:

	Restricted Stock	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2013	3,958,692	$ 1.93
Restricted stock granted	4,343,692	2.69
Restricted stock vested	-	-
Restricted stock forfeited	(15,000)	2.69
Unvested balance at December 31, 2014	8,287,384	$ 2.33

As of December 31, 2014, the Company had unrecognized stock-based compensation expense related to all unvested restricted stock awards of $15.2 million, which is expected to be recognized over the remaining weighted-average vesting period of 3.0 years.

Employee Stock Purchase Plan

On December 19, 2011, the Company's Board of Directors approved the ESPP for the issuance of up to 200,000 shares of Common Stock to eligible employees. Eligible employees can purchase the Company's Common Stock at the end of a predetermined offering period at 85 % of the lower of the fair market value at the beginning or end of the offering period. The first period commenced February 1, 2012 and ended on November 30, 2012. Thereafter offerings will be six months in duration and will commence on each December 1 and June 1. Employee contributions will be made through payroll deductions over the offering period and subject to certain limitations will be used to purchase shares at the end of each offering period. The ESPP is compensatory and will result in stock-based compensation expense. The ESPP was approved by stockholders at the Company's Annual Meeting on August 16, 2012. As of December 31, 2014, 63,194 have been purchased and 136,806 are available for future sale under the ESPP. The Company recognized share-based compensation expense of $25,000, $46,000 and $95,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

On November 30, 2012, the Company issued 21,644 shares of Common Stock in connection with the first ESPP offering period. The shares were issued at $4.02 per share, which represents 85% of the closing price of $4.73 of the Common Stock on November 30, 2012.

On May 31, 2013, the Company issued 21,505 shares of Common Stock under the ESPP. The shares were issued at $3.88 per share, which represents 85% of the closing price of $4.56 of the Common Stock on December 3, 2012.

On December 1, 2013, the Company issued 6,065 shares of Common Stock under the ESPP. The shares were issued at $1.39 per share, which represents 85% of the closing price of $1.64 of the Common Stock on November 29, 2013.

On June 2, 2014, the Company issued 7,139 shares of Common Stock under the ESPP. The shares were issued at $1.45 per share, which represents 85% of the closing price of $1.71 of the Common Stock on June 2, 2014.

On December 1, 2014, the Company issued 6,841 shares of Common Stock under the ESPP. The shares were issued at $1.80 per share, which represents 85% of the closing price of $2.12 of the Common Stock on December 1, 2014.

15. License Agreements

TSO

Under the Ovamed License, the Company is required to make milestone payments to Ovamed totaling up to approximately $5.45 million, contingent upon the achievement of various regulatory milestones for the first product that incorporates TSO, and additional milestone payments upon the achievement of regulatory milestones relating to subsequent indications. In 2011, the IND filed by the Company with the United States Federal Food and Drug Administration ("FDA") became effective resulting in the recognition of a $ 1.5 million obligation due to Ovamed, which was paid in November 2012. In the event that TSO is commercialized, the Company is obligated to pay to Ovamed royalties based on net sales and, if sublicensed, a varying percentage of certain consideration received from the sublicensee.

In addition to the Ovamed Agreements, the Company also entered into the following agreements relating to TSO:

Collaboration Agreements with FU Berlin, Ovamed and Falk

Research Agreement

On February 22, 2013, the Company and Freie Universität Berlin ("Berlin") entered into a Research Agreement (the "Research Agreement") to, among other things, identify and evaluate secretory proteins from TSO (the "Project"). The duration of the Project was expected to be four years, during which the Company would have paid FU Berlin a total maximum amount of approximately €648,000, or approximately $788,000 in research fees and FU Berlin would have periodically produced written progress reports on the Project. On March 25, 2014, the Company terminated the Research Agreement effective June 30, 2014. In connection with this termination, the Company incurred a one-time termination fee of approximately $167,000, comprised primarily of unpaid research fees, which is included in research and development expenses during the year ended December 31, 2014 and approximately $183,000 for the year ended December 31, 2013.

On February 22, 2013, the Company and FU Berlin also entered into a Joint Ownership and Exclusive License Agreement (the "JOELA"), pursuant to which the Company agreed to jointly own all intellectual property arising from the Project (the "Joint Intellectual Property"). FU Berlin also granted the Company (a) an exclusive worldwide license (including the right to sublicense) to its interest in the Joint Intellectual Property and its know-how related to the Project (the "Licensed IP"), and (b) the right to commercialize products that, without the licenses granted under the JOELA, would infringe the Licensed IP (the "Licensed Products"). FU Berlin retains the non-exclusive and non-transferable right to use the Licensed IP for its own internal, academic purposes. Pursuant to the JOELA, the Company will pay FU Berlin a total maximum amount of €3,830,000, or approximately $4,655,000, (based upon the exchange rate at December 31, 2014), in potential milestone payments, based primarily on the achievement of clinical development and regulatory milestones, and royalties on potential net sales of products ranging from 1.0% to 2.5%. The JOELA continues until the last-to-expire patent in any country, subject to early termination by either party without penalty if the other party breaches the JOELA and the breach is not cured within 60 days after receiving notice of the breach or if a party is in bankruptcy. The Company also has the right to terminate the JOELA after giving FU Berlin 60 days written notice of a regulatory action that affects the safety, efficacy or marketability of the Licensed Products or if the Company cannot obtain sufficient materials to conduct trials, or upon 180 days written notice for any reason.

In connection with the Research Agreement and JOELA, the Company entered into a License and Sublicense Agreement (the "LSA") with Ovamed on February 22, 2013, pursuant to which the Company licensed its rights to the Joint Intellectual Property and sublicensed its rights to the Licensed IP to Ovamed in all countries outside North America, South America and Japan (the "Ovamed Territory"). Pursuant to the LSA, Ovamed would pay the Company a total maximum amount of €1,025,000, or approximately $1,246,000, based primarily on the achievement of regulatory milestones, and royalties on potential net sales of products ranging from 1.0% to 2.5%, subject to adjustment, in each case equal to the comparable payments due under the JOELA. The LSA continues until the last-to-expire patent in any country in the Ovamed Territory, subject to early termination by either party upon the same terms as in the JOELA.

On February 22, 2013, Coronado, Ovamed and FU Berlin entered into a Letter Agreement (the "Letter Agreement") to amend a Material Transfer Agreement dated May 14, 2012 by and between Ovamed and FU Berlin. The Letter Agreement provides that Ovamed will retain a 10% interest in FU Berlin's rights to the Joint Intellectual Property in the Ovamed Territory. It also grants Ovamed certain rights if FU Berlin terminates the JOELA due to the Company's breach, including the right to have the JOELA survive and the Company's rights and obligations thereunder assigned to Ovamed.

Manufacturing Agreement

In December 2012, the Company and Ovamed entered into the Second Amendment and Agreement also known as the Manufacturing Agreement, amending certain provisions of the Company's exclusive sublicense agreement and manufacturing and supply agreement with Ovamed. Pursuant to the Manufacturing Agreement, Ovamed granted the Company an exclusive license to make TSO for the Coronado Territory, terminating Ovamed's exclusive supply rights in the Coronado Territory once the Company manufacturing facility in the United States is operational.

In exchange for manufacturing rights, the Company agreed to pay Ovamed a total of $1.5 million in three equal installments of $0.5 million commencing in December 2015 and ending in December 2016. The Company recorded the $1.0 million net present value of these payments as in-process research and development on the accompanying consolidated statement of operations and on its accompanying consolidated balance sheet as a long-term liability. Additionally, in lieu of product supply payments that would have been payable to Ovamed as the exclusive supplier, the Company will pay Ovamed a manufacturing fee for product manufactured and sold by the Company. The manufacturing fee will consist of the greater of (i) a royalty on net sales of product manufactured by us or (ii) a specified amount per unit, or the Transfer Fee Component. The manufacturing fee is subject to certain adjustments and credits and the Company has a right to reduce the Transfer Fee Component by paying Ovamed an agreed amount within ten business days following the FDA approval of a Biologics License Application approving the manufacturing, marketing and commercial sale of TSO. The company has sufficient supply to complete our Phase 2 ASD Study and is assessing options for future supply.

Simultaneously with the execution of the Second Amendment, TSO Laboratories Inc., a wholly owned subsidiary of Ovamed, assigned to the Company a five-year property lease in Woburn, MA for space the Company initially planned to establish a TSO manufacturing facility. Ovamed agreed to assist the Company in establishing this facility and the Second Amendment contemplates that the Company and Ovamed would act as second source suppliers to each other at agreed transfer prices pursuant to a Second Source Agreement to be negotiated between the parties. This facility will be required to meet applicable FDA manufacturing requirements contained in the FDA's current good manufacturing practice standards, or cGMP Good Manufacturing Practice or GMP standards and will be subject to FDA inspections. The Company is currently evaluating its TSO manufacturing plans and will continue to purchase supply from Ovamed, to the extent available. On February 27, 2015, Ovamed filed for insolvency in Germany, a process similar to U.S. bankruptcy. We are currently unable to assess the likelihood of Ovamed continuing operations or being able to continue to supply TSO to the Company.

Dr. Falk Pharma GmbH

In March 2012, the Company entered into a collaboration agreement relating to the development of TSO for CD with Dr. Falk Pharma GmbH ("Falk") and Ovamed (the "Collaboration Agreement"). Pursuant to the Collaboration Agreement, Falk granted the Company exclusive rights and licenses under certain Falk patent rights, pre-clinical data, and clinical data from Falk's clinical trials of TSO in CD, including the ongoing Falk Phase 2 clinical trial, for use in North America, South America and Japan. In exchange, the Company granted Falk exclusive rights and licenses to its pre-clinical data and data from planned clinical trials of TSO in CD for use in Europe.

The Company agreed to pay Falk a total of €5 million (approximately $6.1 million, as of December 31, 2014) after receipt of certain preclinical and clinical data, and a royalty equal to 1% of net sales of TSO in North America, South America and Japan. In March 2012, the Company paid Falk €1 million (approximately $1.2 million, as of December 31, 2014) upon receipt of Falk's pre-clinical data package and recorded this payment as a TSO milestone expense. In April 2012, the Company paid and expensed an additional €1.5 million (approximately $1.8 million) upon receipt from Falk of the recommendation from the independent data monitoring committee that conducted an interim analysis of the Falk Phase 2 trial. The Company currently expects to expense and pay the remaining €2.5 million (approximately $3.0 million as of December 31, 2014) during 2015, upon receipt of the CSR.

Collaboration Agreement

Under the Collaboration Agreement, a steering committee comprised of our representatives and representatives of Falk and Ovamed is overseeing the TSO development program in CD, under which the Company 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 CD in the United States and Europe and will share in certain preclinical development costs.

The Collaboration Agreement may be terminated by either Falk or the Company if the other party fails to cure a material breach under the agreement, subject to prior notice and the opportunity to cure, if the other party is subject to bankruptcy proceedings or if the terminating party terminates all development of TSO.

CNDO–109

In November 2007, the Company entered into a license agreement with the University College London Business PLC ("UCLB") under which the Company received an exclusive, worldwide license to develop and commercialize CNDO–109 for the treatment of cancer-related and other conditions. In consideration for the license, the Company made upfront payments totaling $0.1 million and may be required to make future milestone payments totaling up to approximately $22 million upon the achievement of various milestones related to regulatory or commercial events. In March 2012, the Company recognized a milestone payment of $250,000 to UCLB related to its February 2012 IND filing for CNDO 109 and in April 2012 the Company paid UCLB this milestone. In the event that CNDO–109 is commercialized, the Company is obligated to pay to UCLB annual royalties ranging from 3% to 5% based upon various levels of net sales of the product. Under the terms of the agreement, the Company must use diligent and reasonable efforts to develop and commercialize CNDO–109 worldwide. In June 2012, the FDA granted orphan drug designation to CNDO-109 activated NK cells for the treatment of AML. The Company has exclusive worldwide rights to develop and market CNDO-109 under a license agreement with the University College London Business PLC, or UCLB.

Under the terms of the license agreement, the Company is allowed to grant sublicenses to third parties without the prior approval of UCLB. In the event that the Company sublicenses CNDO–109 to a third party, the Company is obligated to pay to UCLB all or a portion of the royalties the Company receives from the sublicensee.

Unless earlier terminated, the agreement terminates upon the expiration of the last licensed patent right. Either party may terminate the agreement in the event of material breach by the other party, subject to prior notice and the opportunity to cure, or in the event the other party enters into bankruptcy or is dissolved for any reasons other than in connection with a merger or acquisition. UCLB may terminate the license agreement if the Company, or its affiliates, commence or assist in legal proceedings to challenge the validity or ownership of the patents licensed to the Company under the agreement, or if the Company markets or sells a competing product without UCLB's prior written consent. In addition, the Company may terminate the agreement upon 30 days written notice to UCLB.

16. Executive Officer Agreements

Lindsay A. Rosenwald

On December 19, 2013, the Company's Board of Directors appointed Dr. Lindsay A. Rosenwald, as the Chairman, President and Chief Executive Officer. The Company does not intend to enter into any employment contract with Dr. Rosenwald addressing his officer positions with the Company. However, in connection with his appointment as President and Chief Executive Officer, the Company pays Dr. Rosenwald an annual base salary of $28,275. Dr. Rosenwald is also eligible for a discretionary bonus based on his achievement of performance goals and objectives as established by the Board of Directors. In addition, on December 19, 2013, the Company issued Dr. Rosenwald 1,979,346 shares of restricted stock for services to be rendered to the Company. The fair value was $3.8 million based upon a value of $1.93 per share calculated using a Monte Carlo Simulation model, and vests based upon the passage of time and certain pre-defined market conditions and continued employment with or service on the Company's Board of Directors.

Michael S. Weiss

Mr. Weiss has served as a director of the Company since December 19, 2013 and from that time until February 19, 2014 served as the Co-Vice Chairman of the Board of Directors. On February 20, 2014, Mr. Weiss was appointed Executive Vice Chairman, Strategic Development. The Company does not intend to enter into any employment contract with Mr. Weiss addressing his officer positions with the Company and the Company pays Mr. Weiss an annual base salary of $28,275, the lowest salary permissible under New York State law. Mr. Weiss is eligible for a discretionary bonus based on his achievement of performance goals and objectives as established by the Board of Directors. On December 19, 2013, the Company issued Mr. Weiss 1,979,346 shares of restricted stock for services to be rendered to the Company. The fair value was $3.8 million based upon a value of $1.93 per share calculated using a Monte Carlo Simulation model, and vests based upon the passage of time and certain pre-defined market conditions. In addition, on February 20, 2014, the Company issued Mr. Weiss 3,958,692 shares of restricted stock as an inducement to employment and for services to be rendered to the Company. The fair value was $10.6 million and was based on a closing Common Stock price of $2.69 on the date of grant. Such shares shall vest at a rate of 16.67% for the first three annual anniversaries and the remaining 50% will vest in five equal installments of 10% upon certain events occurring.

Malcolm Hoenlein

On February 20, 2014, the Company appointed Mr. Hoenlein to the vacant seat on its Board of Directors. Mr. Hoenlein was granted 30,000 shares of restricted stock, of which one-third vests on each annual anniversary of grant. The fair value was $80,700 and was based on a closing Common Stock price of $2.69 per share on the date of grant.

Harlan F. Weisman

On December 28, 2012, the Company's Board of Directors appointed Dr. Harlan F. Weisman Chairman and Chief Executive Officer. On January 7, 2013, the Company entered into an employment agreement with Dr. Weisman, pursuant to which the Company granted Dr. Weisman an option to purchase 1,686,590 shares of Common Stock at an exercise price of $5.57 per share. One-third of the shares underlying the option were to vest on December 28, 2013 and each annual anniversary thereafter, subject to Dr. Weisman's continued employment with the Company.

On December 19, 2013, Dr. Weisman resigned his position as Chairman and Chief Executive Officer and as a director of the Company and the Company entered into a separation and release agreement. The Company recorded a severance charge of $900,000, all of which had been paid as of December 31, 2014. In addition, the Company will reimburse Dr. Weisman for the cost of his COBRA premiums for 12 months and pay Dr. Weisman $3,450 per month until December 2014 for his living expenses. In accordance with the terms of his employment agreement, an additional one-third of each of Dr. Weisman's outstanding stock awards became automatically vested. On December 19, 2013, the Company extended the exercise period of his vested options from 90 days to two years. The charge related to the modification was approximately $318,000.

Noah D. Beerman, Karin M. Hehenberger and Dale Ritter

On November 5, 2013, the Company terminated certain personnel, including Noah D. Beerman (Executive Vice President and Chief Operating Officer), Dr. Karin M. Hehenberger (Executive Vice President of Scientific Affairs) and Dale Ritter (Senior Vice President, Finance and Chief Accounting Officer), in connection with the Company's effort to lower operating expenses and realign the organization to work more efficiently given the results of the Phase 2 TRUST-I clinical trial for TSO in CD. In connection with these terminations, the Company recorded a severance charge of $479,000 in 2013 and had paid all of the severance obligations as of December 31, 2014. In addition, in accordance with the terms of their employment agreements, an additional one-third of each of Mr. Beerman, Dr. Hehenberger and Mr. Ritter's outstanding stock awards became automatically vested. The charge related to the accelerated vesting of these awards was approximately $390,000.

Kevin Horgan

On November 5, 2013, the Company entered into an executive employment agreement with Dr. Kevin Horgan, its then Chief Medical Officer. Pursuant to the employment agreement, the Company paid Dr. Horgan an annual base salary of $340,000. At the discretion of its Board of Directors, he was also eligible for an annual cash bonus of up to forty percent of his base salary then in effect depending on the attainment of financial, clinical development and/or business milestones to be established by its Board or Compensation Committee. In connection with the execution of the employment agreement, the Company also granted Dr. Horgan an option to purchase 200,000 shares of our Common Stock with an exercise price of $1.71. One-third of the shares underlying the option will vest on each annual anniversary of the grant date, subject to Dr. Horgan's continued employment with the company (see Note 14). Effective January 28, 2014, Dr. Kevin Hogan, was separated from service from the Company. In connection therewith, the Company recorded a severance charge of $0.4 million.

Bobby W. Sandage

On December 28, 2012, Dr. Bobby W. Sandage, Jr. became President of the Company. This change in status from Chief Executive Officer and President to President entitled him to terminate his employment agreement for good reason, in which case the Company would be obligated to pay Dr. Sandage his salary for 12 months. In addition, under the terms of his employment agreement, any options that will vest on the next anniversary date of their respective grant date would automatically vest. Effective December 28, 2012, the Company entered into an amendment to Dr. Sandage's employment agreement pursuant to which he will retain until June 28, 2013, the right to terminate his employment for good reason, be paid his severance allowance equal to his salary for 12 months and have any unvested options vest in full. Also, the amended employment agreement provided that in the event Dr. Sandage terminated his employment for good reason; he will have two years from such termination to exercise his options. In addition, if Dr. Sandage terminates his employment, the Company will be required to pay his COBRA premiums for 12 months after his termination. On April 22, 2013, Dr. Sandage, resigned as president and director of the Company. In accordance with Dr. Sandage's employment agreement, as amended, Dr. Sandage is entitled to receive his salary and COBRA benefits for twelve months from the date of his resignation. The Company recorded a severance liability of $445,000 for these obligations in 2013 and had paid all of the severance obligation as of December 31, 2014.

The change to Dr. Sandage's existing stock options that provided for full vesting of all unvested options in the event he terminated employment prior to June 28, 2013 as well as the extension of time to exercise his options after termination of employment constitutes a modification for accounting purposes. The Company assessed the probability that Dr. Sandage's existing unvested options would vest under their original terms and concluded that it was probable that his unvested options would vest under their original terms. Since Dr. Sandage can choose to terminate his employment as of December 28, 2012 and have all options vest as a result, the Company determined that Dr. Sandage has no future service requirement or requisite service period for the stock options. As a result, all stock-based compensation cost was recognized immediately on December 28, 2012 and the Company recorded a charge to operations of approximately $135,000 representing the remaining unrecognized expense of the original fair value of the options. During 2012, the Company recognized a liability and charge to operations of $200,000 for Dr. Sandage's 2012 performance bonus, all of which was paid as of December 31, 2013.

Strategic Transaction Committee

On February 20, 2014, the Board of Directors established a Strategic Transaction Committee composed of Messrs Lobell, Rowinsky, Harvey and Barrett. In connection with their appointment to the Committee, each member was granted 50,000 shares of Restricted Stock vesting one third on each annual anniversary of grant.

Shareholders' Agreement

On February 20, 2014, Drs. Harvey, Rosenwald and Rowinsky and Messrs. Barrett, Lobell and Weiss, entered into a Shareholders' Agreement, pursuant to which they agreed that, until the end of the Company's annual meeting held in calendar year 2016 and so long as Dr. Rosenwald and Mr. Weiss are on the proposed slate of directors to be nominated, they each will vote all of their shares of Company Common Stock in favor of electing those individuals, and only those individuals, to the Board of Directors whom the Company's Nominating and Corporate Governance Committee proposes. Until that time, they also agreed to not publicly or otherwise advocate for or encourage in any way (outside of fulfilling their director duties) the election of any individual to our board whom is not proposed by the Nominating and Corporate Governance Committee.

17. Income Taxes

The Company has incurred net operating losses since inception. The Company has not reflected any benefit of such net operating loss carryforwards ("NOL") in the accompanying consolidated financial statements and has established a full valuation allowance of $50.6 million against its deferred tax assets.

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The significant components of the Company's deferred tax assets consisted of the following:

	As of December 31,	
	2014	2013
($ in thousands)		
Deferred tax assets:		
Net operating loss carryforwards	$ 38,974	$ 31,450
Amortization of up-front fees	2,668	2,865
Amortization of in-process R&D	525	460
Stock compensation	4,512	2,827
Accruals and reserves	518	854
Tax credits	3,856	2,686
Total deferred tax assets	51,053	41,142
Valuation allowance	(50,567)	(41,142)
Net deferred tax assets	$ 486	$ —
Deferred tax liabilities:		
Unrealized gain/loss on investment	$ (486)	$ —
Total deferred tax assets, net	$ —	$ —

A reconciliation of the statutory tax rates and the effective tax rates is as follows:

	For the Year Ended December 31,		
	2014	2013	2012
Percentage of pre-tax income:			
U.S. federal statutory income tax rate	35%	35%	35%
State taxes, net of federal benefit	5%	4%	4%
Credits	6%	4%	1%
Non-deductible items	(1)%	(2)%	(2)%
Other (1)	—%	(1)%	(5)%
Change in valuation allowance	(45)%	(40)%	(33)%
Effective income tax rate	—%	—%	—%

(1) – Other consists of: in 2014 (0%), in 2013 state NOL true-up (1%), and in 2012 state rate change (5%).

Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. The Company has concluded, based on the weight of available evidence, that its net deferred tax assets are not more likely than not to be realized in the future. Management has considered the Company's history of cumulative net losses incurred since inception and concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2014 and 2013. The valuation allowance increased by $9.4 million from December 31, 2013 to December 31, 2014, primarily due to an increase in net operating losses.

As of December 31, 2014, the Company has federal net operating loss carryforwards and research and development tax credit carryforwards of approximately $104.0 million and $3.8 million respectively, including an orphan drug tax credit of $2.1 million, which expire beginning in 2026 and 2029, respectively. As of December 31, 2014, the Company has state net operating loss carryforwards of approximately $50.7 million, which expires beginning in 2031. Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, or the IRC, and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change under Section 382 of the IRC has occurred. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carryforwards attributable to periods before the change. Any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization. Approximately $1.8 million of the federal net operating loss carryforward and $1.6 million of the state net operating loss carryforward will result in an increase to additional paid-in capital if and when these carryforwards are used to reduce income taxes payable.

As of December 31, 2014, the Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance. The Company would classify interest and penalties related to uncertain tax positions in income tax expense, if applicable. There was no interest expense or penalties related to unrecognized tax benefits recorded through December 31, 2014. The tax years 2006 through 2014 remain open to examination by one or more major taxing jurisdictions to which the Company is subject.

18. Subsequent Events

On January 14, 2015, a wholly owned subsidiary of the Company, Coronado SO Company (“Coronado SO”), entered into an exclusive license agreement with a third party for a license for a Phase 2, topical product used in the treatment of Hand-Foot Syndrome, a common painful side effect of chemotherapeutics. Coronado SO paid $0.9 million upfront and will pay $0.9 million nine months from the execution date. Additional milestone payments are due upon the achievement of certain development milestones and royalties will become due on sales of the product.

On February 18, 2015, the Company purchased an exclusive license to an intravenous (“IV”) formulation of Tramadol for the U.S. market from Revogenex Ireland Ltd (“Revogenex”), a privately held company in Dublin, Ireland. The Company made an upfront payment of $2.0 million to Revogenex upon execution of the exclusive license and Revogenex is eligible to receive additional milestone payments upon the achievement of certain development milestones, in addition to royalty payments for sales of the product. Tramadol is a centrally acting synthetic opioid analgesic for moderate to moderately severe pain and is available as immediate release or extended-release tablets in the United States.

Also, in February 2015, the Company has formed a wholly owned subsidiary, Avenue Therapeutics, Inc., to acquire, in-license, develop and commercialize products principally for use in the U.S. hospital market. The Company will transfer the Revogenex license to Avenue Therapeutics, Inc. Avenue Therapeutics plans to initiate a Phase III development program of IV Tramadol for the management of post-operative pain later this year. Under the terms of the agreement, the Company and Avenue Therapeutics will assume sole responsibility for the development and commercialization of IV Tramadol in the United States. In addition to IV Tramadol, Avenue Therapeutics plans to seek additional products.

On March 2, 2015, the Company announced that it has closed a private placement of a promissory note for $10 million. The Company intends to use the proceeds from the offering to acquire medical technologies and products and create subsidiaries in which it can advance those technologies and products. The note matures in 36 months, provided that during the first 24 months the Company can extend the maturity date by six months. No principal amounts will be due for the first 24 months (or the first 30 months if the maturity date is extended). Thereafter, the note will be repaid at the rate of 1/12 of the principal amount per month for a period of 12 months. The note bears an 8% coupon payable quarterly during the first 24 months (or the first 30 months if the note is extended) and monthly during the last 12 months. National Securities Corporation, a wholly owned subsidiary of National Holdings, Inc., acted as the sole placement agent for the offering. The note was sold in the private placement pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The note has not been registered under the Securities Act, or the securities laws of any other jurisdiction, and may not be offered or sold in the United States absent registration or an applicable exemption from such registration requirements.

On March 4, 2015 we announced the formation of a new subsidiary company, Checkpoint Therapeutics, Inc., to develop a portfolio of fully human immuno-oncology targeted antibodies generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a Professor in the Department of Cancer Immunology and AIDS at the Dana-Farber Cancer Institute ("Dana-Farber"). Dr. Marasco will chair the Scientific Advisery Board of the Company. Under the terms of the agreement, Checkpoint will pay Dana-Farber an up-front licensing fee in addition to development and sales-based milestone payments and royalties on net sales. The portfolio of antibodies licensed from Dana-Farber includes antibodies targeting PD-L1, GITR and CAIX. Checkpoint plans to develop these novel immuno-oncology and checkpoint inhibitor antibodies on their own and in combination with each other, as data suggests that combinations of these targets can work synergistically together. Clinical trials are expected to start in the second half of next year. In connection with the license agreement with Dana-Farber, Checkpoint Therapeutics entered into a collaboration agreement with TG Therapeutics, Inc. to develop and commercialize the Anti-PD-L1 and Anti-GITR antibody research programs in the field of hematological malignancies.

Mr. Weiss, the Company's Executive Vice President, Strategic Development, and Co-Portfolio Manager and Partner of OPPM with Dr. Rosenwald, is the Executive Chairman, Interim Chief Executive Officer and stockholder of TG Therapeutics, Inc. Checkpoint retains the right to develop and commercialize these antibodies in solid tumors. Both programs are currently in pre-clinical development. Under the terms of the agreement, TG Therapeutics will pay Checkpoint an up-front licensing fee as well as make development and sales-based milestone payments and will pay a tiered single digit royalty on net sales.

On March 10, 2015, JMC entered into a license and supply agreement to acquire rights to distribute a generic dermatological product. JMC made an upfront payment of $1,250,000 and will incur another fee of $750,000 upon receipt of product. Further payments will be made based on a revenue sharing arrangement.

19. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for fiscal years 2014 and 2013. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented.

(in thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2014				
Operating expenses	$ (6,582)	$ (4,763)	$ (4,346)	$ (4,961)
Other income/(expense)	$ (788)	$ 52	$ (246)	$ 1,248
Net loss	$ (7,370)	$ (4,711)	$ (4,592)	$ (3,713)
Basic and diluted net loss per common share	$ (0.21)	$ (0.13)	$ (0.13)	$ (0.10)
2013				
Operating expenses	$ (8,458)	$ (10,294)	$ (7,504)	$ (9,524)
Other income/(expense)	$ (400)	$ (376)	$ (328)	$ (274)
Net loss	$ (8,858)	$ (10,670)	$ (7,832)	$ (9,798)
Basic and diluted net loss per common share	$ (0.35)	$ (0.38)	$ (0.24)	$ (0.27)

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Coronado Biosciences, Inc.

By: /s/ Lindsay A. Rosenwald, M.D.
Name: Lindsay A. Rosenwald, M.D.
Title: Chairman, President and Chief Executive Officer
March 16, 2015

POWER OF ATTORNEY

We, the undersigned directors and/or executive officers of Coronado Biosciences, Inc., hereby severally constitute and appoint Lindsay A. Rosenwald, M.D., acting singly, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or appropriate to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Lindsay A. Rosenwald, M.D. Lindsay A. Rosenwald, M.D.	Chairman of the Board of Directors, President and Chief Executive Officer (*principal executive officer*)	March 16, 2015
/s/ Lucy Lu, M.D. Lucy Lu, M.D.	Executive Vice President and Chief Financial Officer (*principal financial officer*)	March 16, 2015
/s/ Eric K. Rowinsky, M.D. Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	March 16, 2015
/s/ Michael S. Weiss Michael S. Weiss	Executive Vice Chairman, Strategic Development and Director	March 16, 2015
/s/ David J. Barrett David J. Barrett	Director	March 16, 2015
/s/ Jimmie Harvey, Jr., M.D. Jimmie Harvey, Jr., M.D.	Director	March 16, 2015
/s/ J. Jay Lobell J. Jay Lobell	Director	March 16, 2015
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 16, 2015

EXHIBIT 21.1

SUBSIDIARIES OF CORONADO BIOSCIENCES, INC.

Subsidiaries of Coronado Biosciences, Inc. at December 31, 2014:

- Altamira Bio Inc., formerly TSO Development Corporation, Inc.
- CB Pharma Acquisition Corp.
- CB Securities Corporation
- Coronado SO Co., Inc.
- Cyprium, Inc.
- Innmune Limited
- Journey Medical Corporation

Additional subsidiaries of Coronado Biosciences, Inc. formed after December 31, 2014:

- Avenue Therapeutics, Inc.
- Checkpoint Therapeutics, Inc.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Coronado Biosciences, Inc. on Form S-3 (Nos. 333-177041, 333-183943 and 333-189935) and Form S-8 (No. 333-184616 and 333-194588) of our report dated March 16, 2015, on our audit of the consolidated financial statements as of December 31, 2014 and for the year then ended, and the effectiveness of internal control over financial reporting as of December 31, 2014, which reports are included in this Annual Report on Form 10-K to be filed on or about March 16, 2015.

/s/ EisnerAmper LLP

New York, New York
March 16, 2015

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-184616 and 333-194588) and Form S-3 (Nos. 333-177041, 333-183943 and 333-189935) of Coronado Biosciences, Inc. of our report dated March 14, 2014 relating to the financial statements that appear in this Form 10-K.

/s/ PricewaterhouseCoopersLLP

Boston, Massachusetts
March 16, 2015

EXHIBIT 31.1

CERTIFICATION PURSUANT TO

SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lindsay A. Rosenwald, M.D. certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2014 of Coronado Biosciences, Inc. (the registrant);

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 16, 2015

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION PURSUANT TO

SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lucy Lu, certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2014 of Coronado Biosciences, Inc. (the registrant);

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 16, 2015

By: /s/ Lucy Lu
Lucy Lu
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO

18 U.S. C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Coronado Biosciences, Inc. (the "Company") for the period ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lindsay A. Rosenwald, M.D., Chairman, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

Dated: March 16, 2015

By:/s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S. C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Coronado Biosciences, Inc. (the "Company") for the period ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lucy Lu, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company, as of, and for, the periods presented in the Report.

Dated: March 16, 2015

By: /s/ Lucy Lu
Lucy Lu
Chief Financial Officer