2013 Annual Report

Included in the 2013 Annual Report:
Form 10-K filed with the U.S. Securities and Exchange Commission on
March 14, 2014

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, 2013

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 **(State or Other Jurisdiction of Incorporation or Organization)**	**20-5157386** **(I.R.S. Employer Identification No.)**
24 New England Executive Park, Suite 105 **Burlington, MA** **(Address of Principal Executive Offices)**	**01803** **(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: $162,039,807 based upon the closing sale price of our common stock of $8.60 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 12, 2014, there were 44,086,387 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2014 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2014 are incorporated by reference into Part III hereof.

[This page intentionally left blank.]

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

[This page intentionally left blank.]

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;
- the results of research and development activities;
- uncertainties relating to preclinical and clinical testing;
- financing and strategic agreements and relationships;
- the early stage of products under development;
- our need for substantial additional funds and uncertainties relating to financings;
- our ability to attract, integrate and retain key personnel;
- our ability to manufacture our product;
- 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, 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 plan to identify, evaluate and potentially in-license, acquire or invest in pharmaceutical and biotechnology products, technologies and/or companies. We may also from time to time consider financing existing or later-acquired products, technologies or companies through partnerships, joint ventures, direct financings, and/or public or private 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.

TSO

CNDO-201 is a biologic comprising the microscopic eggs of the porcine whipworm, which we believe could be used for the treatment of a range of autoimmune diseases, such as Crohn's disease or CD, ulcerative colitis or UC, multiple sclerosis or MS, autism, psoriasis and Type 1 diabetes or T1D.

In February 2012, we announced positive results from our Phase 1 clinical trial of TSO in 36 patients with 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. To date, a number of investigator-sponsored clinical trials have been conducted using TSO in patients suffering from CD, UC, MS, autism and psoriasis. These studies also demonstrated that TSO is safe and well tolerated.

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 ova (N=125) or placebo (N=125) once every two weeks for 12 weeks. In October 2013, we reported that the TRUST-I study did not meet its primary endpoint of improving response, defined as a 100-point decrease in the CD Activity Index ("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 pre-defined subset analysis in patients with baseline CDAI > 290 (N=121), TSO showed a non-significant improved response. The lack of overall response was driven by a higher-than-expected placebo response rate in patients with CDAI < 290. TSO was safe and well-tolerated, and adverse events were balanced between the TSO and the placebo group. The most common adverse event reported was abdominal pain and occurred in 11% of both TSO and placebo groups.

In November 2013, Dr. Falk Pharma GmbH ("Falk"), our development partner, informed us that an independent data monitoring committee ("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.

We have the exclusive rights to TSO in North America, South America and Japan (the "Coronado Territories") under a sublicense agreement with Ovamed GmbH, or Ovamed, as well as a manufacturing and supply agreement with Ovamed to provide us with our clinical and commercial requirements of TSO. In December 2012, we signed the Second Amendment and Agreement to our sublicense agreement with Ovamed, which provides us the exclusive right to manufacture TSO for the Coronado Territories in exchange for certain consideration to Ovamed. We anticipate in the near term continuing to purchase TSO supplies from Ovamed, as a result of the outcome of TRUST-I. We are currently evaluating our TSO manufacturing plans.

In March 2012, we entered into a Collaboration Agreement with Ovamed and Falk, Ovamed's sublicensee in Europe for gastroenterology indications, under which we agreed to collaborate in the development of TSO for CD. Under the Collaboration Agreement, Falk granted us exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO in CD, including Falk's ongoing Phase 2 clinical trial, for use in North America, South America and Japan. We granted Falk exclusive rights and licenses to data from our clinical trials of TSO in CD for use in Europe. A steering committee comprised of our representatives and representatives of Falk and Ovamed is overseeing the clinical 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.

On February 22, 2013, we and Freie Universität Berlin ("FU Berlin") entered into a Research Agreement to, among other things identify and evaluate secretory proteins from TSO. The duration of the project is expected to be four years, during which time the Company will pay FU Berlin a total maximum amount of approximately $853,000 in research fees, commencing February 2013 and ending January 2017. Through December 31, 2013, we paid approximately $183,000 in research fees. We also entered into several license agreements regarding intellectual property that may result from this research. (See Note 14 of Notes to Consolidated Financial Statements.)

In December 2013, we announced that we submitted an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") to begin a Phase 2 clinical study of TSO for the treatment of moderate-to-severe chronic plaque psoriasis. We also held a pre-IND meeting with the FDA regarding TSO for the treatment of autism.

Until we have fully analyzed the TRUST-I trial data, have received, reviewed and fully analyzed the results of the TRUST-II trial, and have determined the development path, if any, for TSO, we cannot give any assurances as to the future development of TSO, the indications for which TSO could be a treatment, or the costs and timelines for any development plans.

CNDO-109

CNDO-109 is a biologic that activates the immune system's natural killer, or NK, cells to seek and destroy cancer cells. We intend to study CNDO-109 initially in patients that have been diagnosed with acute myeloid leukemia, or AML. Preclinical studies have demonstrated that CNDO-109 activated NK cells directly kill cells that cause hematologic malignancies including myeloid leukemia and multiple myeloma, as well as breast, prostate and ovarian cancers. Eight patients with high-risk AML received CNDO-109 activated NK cells in a recent Phase 1 investigator-sponsored trial. Although the primary endpoint of the Phase 1 clinical trial was safety, based on the data obtained from this Phase 1 study, we believe early efficacy was observed. The clinical investigators observed that the majority of patients experienced a longer complete remission than their previous complete remission. In February 2012, we filed an Investigational New Drug application, or IND, for a multi-center Phase 1/2 clinical trial in patients with relapsed AML. In November 2012, we initiated this trial. In June 2012, the FDA granted orphan drug designation to CNDO-109 activated NK cells for the treatment of AML and, in September 2012, the U.S. Patent and Trademark Office granted the first U.S. patent covering CNDO-109. 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. In 2013, we enrolled three patients in the Phase 1/2 trial, which is on-going.

Industry

Immunology Therapeutics Markets

Autoimmune diseases represent a diverse collection of diseases in terms of their demographic profile and primary clinical manifestations. The phenotypic commonality between them, however, is the damage, driven by a dysfunctional immune system, to tissues and organs that arises from the loss of tolerance or recognition of "self." Autoimmune disorders include inflammatory bowel disease, or IBD, such as CD and UC, MS, autism, psoriasis, and T1D.

According to a 2012 *Decision Resources* report, in the United States and Japan, the estimated prevalence of CD was 534,000 patients, UC was 669,000 patients and MS was 485,000 patients. Autism statistics from the U.S. Centers for Disease Control and Prevention, or CDC, identify around 1 in 88 American children as on the autism spectrum–a ten-fold increase in prevalence in 40 years. According to the National Psoriasis Foundation, psoriasis is the most prevalent autoimmune disease in the United States affecting as many as 7.5 million Americans. According to the 2011 National Diabetes Foundation Fact Sheet (released January 26, 2011 by the American Diabetes Association), nearly 26 million Americans have diabetes and between 5-10% or up to 2.5 million have T1D. Prevalence rates for all autoimmune disorders are expected to continue to rise in the next several years. Each of these diseases is believed to be associated with an excessive inflammatory response and dysfunctional immune system, including abnormal activity of T regulatory ("Treg") cells.

CD is characterized by inflammation of the gastrointestinal tract that causes painful and debilitating symptoms. Most patients with CD experience relapses, and no current therapy is completely effective in preventing acute flares. Although immunosuppressants and TNF-inhibitors are effective maintenance therapies, according to an article published in *Alimentary Pharmacology & Therapeutics* in 2011, fewer than 50% of patients maintain long-term remission with these drugs. According to a 2007 article in *Surgical Clinics of North America*, a significant percentage of CD patients require surgery during their lifetime despite available therapies. Therefore, we believe the greatest unmet need is for more effective maintenance therapies that are also safe for long-term use.

The etiology and pathophysiology of UC are not fully understood, but research appearing in several industry publications, including *Inflammatory Bowel Disease* (2006) and the *World Journal of Gastroenterology* (2006), strongly suggests that genetic susceptibility and environmental factors, coupled with an abnormal immune response, contribute to the development of the disease. Despite significant advances in the understanding of genetic susceptibility and its role in IBD, novel, targeted therapies for the treatment of UC have yet to be identified. We believe the need for safe and more effective maintenance therapies with sustained long-term efficacy are the greatest unmet need in the management of UC.

MS is an autoimmune inflammatory disease of the central nervous system that is characterized by progressive neuronal loss that manifests clinically as worsening physical disability. The key pathophysiological hallmark of MS is the loss of myelin, a layer of lipids and proteins produced by cells called oligodendrocytes that wrap around the neuron and act like an insulating sheath to facilitate electrical conduction along the nerve. Destruction of myelin by an inflammatory cascade leads to neuronal degeneration. As a result, we believe that there is a substantial unmet need for effective treatments for chronic progressive MS as well as a need for therapies that are more conveniently delivered (e.g., oral agents and less-frequently administered injectable drugs).

Autism is a disorder of neural development characterized by impaired social interaction, impaired social communication, and restricted and repetitive behavior. The diagnostic criteria require that symptoms become apparent before a child is three years old. Autism affects information processing in the brain by altering how nerve cells and their synapses connect and organize. How this occurs is not well understood. It is one of three recognized disorders in the autism spectrum, the other two being Aspberger syndrome, which lacks delays in cognitive development and language, and pervasive development disorder, not otherwise specified, which is diagnosed when the full set of criteria for autism or Asperger syndrome are not met. Increasingly, researchers are looking at the role of the immune system in autism. Intervention can involve behavioral treatments, medicines or both. There are no FDA-approved medicines for treating all three core symptoms of autism, but there are two drugs for treating the irritability associated with autism (risperidone – Risperdal; and aripiprazole—Abilify).

Psoriasis (psoriasis vulgaris) is a chronic inflammatory skin disease characterized by red, scaly, raised plaques. The disease process is driven by T-cell infiltration and associated elevation in cytokine levels leading to increased cell division and aberrant differentiation, resulting in the psoriatic phenotype. While many patients with mild disease are able to control psoriasis symptoms with topical medications alone, patients with moderate to severe disease usually require treatment with systemic agents to achieve good clearance. These systemic agents are usually well tolerated, but can have potentially significant side effects including organ toxicity, infection, malignancy, and teratogenicity that limit their usefulness in the long-term management of psoriasis.

Diabetes mellitus is the condition defined by the body's inability to regulate blood glucose (sugar) levels. There are two major types of diabetes, T1D and type 2 diabetes, or T2D. T1D, also called juvenile diabetes or insulin-dependent diabetes, is a disorder of the body's immune system. T1D occurs when the body's immune system attacks and destroys the beta cells in the pancreas. These cells are located within small islands of endocrine cells called the pancreatic islets. Beta cells normally produce insulin, a hormone that helps the body move the glucose contained in food into cells throughout the body, which use it for energy. But when the beta cells are destroyed, no insulin can be produced, and the glucose stays in the blood instead, where it can cause serious damage to all the organ systems of the body. Insulin is currently the major treatment for people with T1D, and exists as short, medium and long-acting version. A relatively small number of people also use Symlin (pramlintide acetate) injections to help normalize their blood sugar.

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.

Our Existing Product Candidates

TSO

TSO is a biologic product candidate for the treatment of autoimmune diseases. We currently plan to investigate TSO for the treatment of CD, UC, MS, autism spectrum disorder, and plaque psoriasis.

Background

The rationale for performing research with helminths initially was based on the hygiene hypothesis postulating that multiple exposures to parasites and pathogens in childhood can protect an individual from allergic and autoimmune disease later in life, whereas individuals raised in a more sanitary environment are more likely to develop autoimmune diseases and allergies. These hypotheses and several studies suggest that exposure to helminth parasites which have followed human evolution may protect against and treat autoimmune disorders. This hygiene hypothesis is based on epidemiologic findings of an inverse relationship between autoimmune diseases and helminthic colonization. According to articles published in the *New England Journal of Medicine* in 2002 and *Inflammatory Bowel Disease* in 2009, the incidence of autoimmune disease is highest in the developed world and in temperate climates, with positive correlations noted among persons of higher socioeconomic status and high levels of domestic hygiene experienced in childhood.

Furthermore, the incidence of autoimmune disease has increased over the past several decades, while the prevalence of helminths in the United States and Europe has steadily declined during the same time period. These findings have led to the hypothesis that eliminating intestinal helminths in the industrialized world has eliminated a natural T regulatory cell mechanism that prevents excessive T-cell activation such as occurs in IBD as well as in other immune-mediated diseases such as MS and allergies.

The immunologic basis for helminth therapy is derived from experimental animal and human data demonstrating that these organisms alter immune responses beyond those directed against the worms. In animal models, helminths blunt Th1 responses and promote Th2 responses associated with increased production of IL-4 and IL-3. Helminthic colonization in humans can result in diminished Th1 immune responses to challenges with unrelated antigens, as well as increased production of immunomodulatory molecules such as IL-10, transforming growth factor (“TGF”)-ß, and regulatory T-cells. Thus, as noted in the *National Review of Immunology* in 2007, genetically susceptible persons who are never exposed to helminths may lack a strong Th2 immune response and develop a poorly regulated and destructive intestinal Th1 response, leading to chronic colitis or ileitis.

The study of TSO as it relates to autoimmune disease 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 the parasitic helminth, or worm, infections in the prevention of inflammatory diseases. Dr. Weinstock is a consultant of our Company . Certain of his colleagues, namely David Elliott, M.D., Ph.D., and William Sanborn, M.D. are also consultants of our Company.

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 able to colonize in a human host for several weeks before being eliminated from the body without the need for antihelminthic therapy. As reported TSO has potential for being a natural immune system modulator without significant risk of causing disease in humans. Mature *T. suis* produce ova that exit the porcine host with the stool, however, we believe ova are not infective until incubating in the soil for several weeks, thereby preventing direct host-to-host transmission. We believe that no human diseases have been associated with exposure to *T. suis* or TSO.

Third Party Clinical Trials

A number of studies have been performed by independent investigators in small samples of patients across a range of diseases with an immune component. These studies evaluated the safety, tolerability and efficacy of TSO treatment.

The first phase I trial was reported in 2003 (Summers, *American Journal of Gastroenterology*), and included seven patients with refractory IBD (four patients with active CD and three patients with UC). Patients received a single dose of 2500 live TSO orally with 30 ml of Gatorade (Gatorade, Chicago, IL). After a treatment and observation period of at least 12 weeks, two patients with CD and two patients with UC were given additional doses of 2500 ova at three-week intervals in a maintenance period. Efficacy was assessed by improvement in the common clinical indices used to describe disease activity. During the treatment and observation period, all patients improved clinically without any adverse clinical events or laboratory abnormalities. Three of the four patients with CD entered remission while the fourth patient experienced a clinical response. Patients with UC experienced a reduction of the Clinical Colitis Activity Index to 57% of baseline. According to the IBD Quality of Life Index (Irvine et al., 1994), six of seven patients (86%) achieved remission by 8.3 weeks following their dose. The benefit derived from the initial dose was temporary, with the mean length of remission for the six patients who attained it approximately eight weeks. During the one-year maintenance period, multiple doses caused no adverse effects and sustained clinical improvement was observed in each of the four patients treated every three weeks for >28 weeks. While the benefit of treatment appeared temporary with a single dose, it was prolonged with maintenance therapy every three weeks for more than 1 year.

An open label, single-arm, phase II trial was conducted by Summers (*Gut*, 2005), with 29 patients with active CD. Over a period of 24 weeks, subjects returned every three weeks to drink the TSO suspended in a commercial drink. Dosing of all other inflammatory bowel disease medications was held constant. Disease activity was monitored by CDAI (Best et al., 1976). Remission was defined as a decrease in CDAI to less than 150 while a response was defined as a decrease in CDAI of greater than 100 points. Most patients responded and achieved remission. At week 12, the response rate was 75.9% and 19 of 29 patients (65.5%) showed complete remission. By week 24, the response rate was 79.3% and at this point 21 of 29 patients (72.4%) were in remission. Gender, patient age, disease duration, smoking status, or disease location had no influence on the frequency of response or remission. There was a trend for patients using immunosuppressive drugs to improve to a greater degree than those not using these agents.

A 12-week, randomized, two-arm, placebo-controlled double-blinded single center study was conducted by Summers and Elliot (*Gastroenterology*, 2005, and *Current Opinions in Gastroenterology*, 2005), with 54 patients with active UC; this study was followed by a 12-week crossover phase for patients who had not responded during the initial treatment period. The Ulcerative Colitis Disease Activity Index ("UCDAI") (Walmsley et al., 1998) that assesses four variables assessed disease activity: stool frequency, severity of bleeding, mucosal appearance, and the physician's overall assessment of the disease activity, were used to assess efficacy. Active disease was defined by an UCDAI >four. Patients were treated with either TSO 2500 or matching placebo for up to 12 weeks. Improvement was defined as a decrease in UCDAI of at least four points. Clinical remission was defined by an UCDAI <2. After 12 weeks of treatment, 43.3% of patients treated with TSO achieved response compared to 16.7% in the placebo group ($p=0.04$, intention-to-treat analysis). Post hoc exploratory analyses of clinically relevant end points were performed by using the 4 components of the UCDAI (frequency of diarrhea, blood in stool, mucosal appearance, and overall assessment of clinical response). With the intention-to-treat analysis, ova-treated patients had significant improvements in stool frequency ($p=0.0011$), blood in the stool ($p=0.0413$), mucosal appearance ($p<0.001$), and overall assessment ($p=0.0011$) compared with their baseline values. The mean UCDAI decreased from 8.77 ± 0.35 to 6.1 ± 0.61 ($p=0.0004$) over the 12-week study. The placebo-treated subjects showed significant improvement only in stool frequency ($p=0.0488$). Their mean UCDAI decreased from 8.75 ± 0.46 to 7.5 ± 0.66 ($p=0.1167$).

The trial included a second 12-week double-blind crossover phase. Patients who were given placebo for the first 12 weeks and who were not in remission (n=17) were switched to T. suis for a second 12 week interval. Patients who initially received TSO and did not achieve remission (n=15) switched to placebo. At the end of the second phase, 56.3% of patients given TSO responded, whereas only 13.3% improved on placebo ($p=0.02$) (Elliott personal communication). Combining data from both 12-week periods indicated response rates of 47.8% with ova and 15.4% with placebo ($p=0.002$).

In a study reported in the *Multiple Sclerosis Journal* in 2011, Dr. John Fleming and his colleagues at the University of Wisconsin studied five subjects with newly diagnosed, treatment-naïve, relapsing–remitting multiple sclerosis, or RRMS. The patients were given 2500 TSO orally every two weeks for three months in a baseline versus treatment controlled trial. The study showed that the mean number of new gadolinium- enhancing magnetic resonance imaging, or MRI, lesions (n-Gdþ) fell from 6.6 at baseline to 2.0 at the end of TSO administration, and two months after TSO was discontinued, the mean number of n-Gdþ rose to 5.8 new lesions. No significant adverse effects were observed. In preliminary immunological investigations, increases in the serum level of the cytokines IL-4 and IL-10 were noted in four of the five subjects. These first five patients represented the first part of a 2-part study (known as HINT-1 and HINT-2). Additional patients are currently being studied for up to 10 months. Results from this second cohort are expected in the first half of 2014.

In studies presented by Dr. John Fleming and by Professor Per Soelberg Soerensen at the American Academy of Neurology in New Orleans on April 25, 2012, TSO was observed to be safe and well tolerated in MS patients, suggesting that TSO would be safe to use in indications other than IBD. Abstracts for these studies, entitled "Temporal Changes in MRI Activity, Inflammation, Immunomodulation, and Gene Expression in Relapsing-Remitting Multiple Sclerosis Subjects Treated with Helminth Probiotic *Trichuris Suis*" (Fleming) and "*Trichuris Suis* Ova Therapy for Relapsing Multiple Sclerosis—A Safety Study" (Soerenson) are available on the American Academy of Neurology 2012 Annual Meeting website.

In March 2012, we signed a Collaboration Agreement with Falk and Ovamed for the development of TSO for CD. Under the Collaboration Agreement, Falk granted us exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO in CD, including Falk's ongoing Phase 2 clinical trial, for use in North America, South America and Japan. We granted Falk exclusive rights and licenses to data from our clinical trials of TSO in CD for use in Europe. Under the agreement, we agreed to pay Falk (i) a total of €5 million (approximately $6.5 million) after receipt of certain pre-clinical and clinical data, of which €2.5 million (approximately $3.4 million) was paid in 2012 and the remaining €2.5 million is expected to be paid in the first half of 2014 upon receipt of the Clinical Study Report ("CSR") and (ii) a royalty of 1% of net sales of TSO in North America, South America and Japan. A steering committee comprised of our representatives and representatives of Falk and Ovamed is overseeing the clinical 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.

In November 2013, we received from Falk a notification that their independent data monitoring committee had conducted an interim analysis (blinded to Falk) of clinical data from approximately 240 patients in Falk's Phase 2 clinical trial in Europe evaluating TSO in CD. The study was a double-blind, randomized, placebo-controlled, multi-center trial to evaluate the efficacy and safety of three different dosages of oral TSO in patients with active CD. The committee noted no safety concerns but recommended that the study be stopped due to a lack of efficacy. Falk adopted the committee's recommendations and discontinued the study.

In December 2013, 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 and Einstein, presented interim data from his pilot study of oral TSO (Trichuris suis ova or CNDO-201) to treat autism at the American College of Neuropsychopharmacology Annual Meeting in Hollywood, Florida. The study is a double-blind, randomized, placebo-controlled, cross-over study and enrolled 10 high-functioning adult autism spectrum disorder 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. They 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 2,500 ova once every two weeks. In the first five patients that completed the study, there was a statistically significant separation from placebo in favor of TSO on three measures of disease: the Montefiore-Einstein Rigidity Scale, the Repetitive Behavior Scale-Revised Sameness Scale, and the Social Responsiveness Scale -Repetitive Behaviors Scale. The treatment was well tolerated. The study is still ongoing and final results are expected in the middle of 2014.

There are also additional ongoing or proposed investigator-initiated clinical trials evaluating TSO in various indications, including UC, MS, autism, and psoriasis. We publicly announced the start of two new trials in 2012, one at the New York University School of Medicine ("NYU"), with Drs. Michael Poles, P'ng Loke and Martin Wolff in UC, and the other at Montefiore in New York City, with Dr. Eric Hollander in autism. We also issued a statement about the agreement with the National Institute of Health's Allergy and Immunology Department, NIAID in UC, with the principal investigator being Dr. Steven Hanauer, Chicago. All three trials are investigator initiated, but we will provide TSO and have worked closely with the investigators to develop protocols and data management tools. We will continue to work with these sites throughout the trials as part of our overall clinical strategy for TSO. In the first quarter of 2013, we announced the start of an open-label trial in psoriasis, and named the first site of three sites, Mt. Sinai School of Medicine. We intend to support certain of these investigator-initiated trials by providing product supply and, in some cases, grants.

Our Clinical Trial Program

In February 2012, we announced positive results from our Phase 1 clinical trial of TSO in patients with CD and the full study results were presented in May 2012 by Dr. David Elliott, Professor and Director of the Gastroenterology and Hepatology Division at the University of Iowa, as a poster at the 8th International Congress on Autoimmunity in Granada, Spain. The Phase 1 clinical trial was a multi-center, sequential dose-escalation, double-blind, placebo-controlled study. The primary objective of the study was to evaluate the safety and tolerability of TSO. The trial enrolled 36 patients with CD ranging in age from 20 to 54 with an equal distribution of male and female patients in three single dose cohorts of orally administered 500, 2500 and 7500 ova. Each cohort had twelve patients, with nine patients receiving TSO and three receiving placebo. Primary safety assessments were determined at day 14 post-dose.

Overall, TSO was found to be safe and well tolerated across all three dose levels tested. There were only two adverse events (metallic taste and sour taste) that were considered to be study drug related as assessed by the investigators, one reported in the 7,500 ova dose group and the other in a patient receiving placebo, respectively. All other reported events were assessed as unrelated to study drug and were self-limiting. Mild gastrointestinal side effects such as nausea (in one placebo-treated patient and two TSO-treated patients) and diarrhea and/or abdominal pain (in two TSO-treated patients) were reported. Safety laboratory values were assessed throughout the study and no clinically significant adverse trends were observed and no laboratory- related adverse events were reported. There were no serious adverse events reported and no patient discontinued the study prematurely.

In August 2012, we initiated our TRUST-I trial, a phase 2 clinical trial of TSO designed to evaluate the safety and efficacy of TSO (7500 ova) given once every two weeks for 12 weeks, in approximately 220 patients with CD.

In October 2013, we reported that the TRUST-I study did not meet its primary endpoint of improving response (where response was 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 lack of overall response was driven by a higher-than-expected placebo response rate. TSO was safe and well-tolerated, and adverse events were balanced between the TSO and the placebo group. The most common adverse event reported was abdominal pain and occurred in 11% of patients in each treatment group.

In December 2013, we announced that we had submitted an IND application to the FDA to begin a Phase 2 clinical study of TSO for the treatment of moderate to severe chronic plaque psoriasis. We also conducted a pre-IND meeting with the FDA regarding TSO for the treatment of autism.

In addition to the studies described above, we may conduct pilot studies and support certain investigator initiated clinical trials of TSO in these and other autoimmune diseases.

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 then are 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 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 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 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 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 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 build out of the office area in the Woburn facility. However, based upon TRUST-I results in October 2013, we are currently evaluating our TSO manufacturing plans. It will take approximately one year to complete the manufacturing site and will require an incremental investment from Coronado. Once complete, 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.

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.

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.

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 first complete remission (CR1) who are deemed 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. In 2013, we enrolled three patients in the Phase 1/2 trial, which is on going. To date, no DLTs have been observed. We are also considering participation in a Phase 1/2 multiple myeloma trial using autologous NK cells, which we believe may initiate in 2014 and selected pilot Phase 1 clinical trials in other tumor types, including breast, prostate and ovarian cancer, with both allogeneic and autologous cells.

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. 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 or PCT. We have entered into master service agreements with both companies as well as a supply agreement with PCT. The master service agreements provide the general framework for the relationships, with specific terms to be established in connection with particular projects. Indirectly, we also rely on Miltenyi Biotec GmbH to provide the equipment and reagents necessary for the identification and selection of NK cells.

Strategic Alliances and Commercial Agreements

TSO

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, 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 currently expires in March 2014 but will automatically renew for successive one-year periods, 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.

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 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.

As part of the Second Amendment, 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 will consist of the greater of (i) a royalty on net sales of product manufactured by us or (ii) a specified amount per unit (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 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 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 build out of the office area in the Woburn facility. However, based upon TRUST-I results in October 2013, we are currently evaluating our TSO manufacturing plans. It will take approximately one year to complete the manufacturing site and will require an incremental investment from Coronado. Once complete, 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.

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 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 was paid in 2012 and half of which is 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.

Under the Collaboration Agreement, a Steering Committee comprised 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 until the evaluation of TRUST-II results in the second quarter of 2014.

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, the Company 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 the Company will pay FU Berlin a total maximum amount of approximately €648,000, or approximately $853,000, 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 the Company terminates the Research Agreement, the Company must pay FU Berlin a termination fee comprised 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, the Company and FU Berlin also entered into a Joint Ownership and Exclusive License Agreement or JOELA, pursuant to which the Company agreed to jointly own all intellectual property arising from the Project, which we refer to as 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, 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, the Company must pay FU Berlin a total maximum amount of approximately €3,830,000, or approximately $4,982,000, 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% 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, or LSA, with Ovamed, on February 22, 2013, pursuant to which the Company licensed is 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, which we refer to as the Ovamed Territory. Pursuant to the LSA, Ovamed would pay the Company a total maximum amount of approximately €1,025,000, or approximately $1,333,000 based primarily on the achievement of regulatory milestones, and royalties on potential net sales of products ranging from 1% 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 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.

In 2013, the Company made two payments totaling approximately $183,000 to FU Berlin in accordance with the term of the Research Agreement.

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 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 reasons 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.

Services Agreement with PCT

In April 2010 and as amended in September 2012, we entered into a Master Contract Services Agreement with Progenitor Cell Therapy ("PCT") pursuant to which PCT may provide consulting, preclinical, laboratory and/or clinical research-related services, product/process development services, manufacturing services and other services to us in connection with the CNDO-109 development program. PCT is currently performing services related to the manufacturing of CNDO-109. We pay for services under the agreement pursuant to statements of work entered into from time to time. Any product resulting from the services performed or product improvement, inventions or discoveries, including new uses for product resulting from the services performed and related patent rights which arise as a result of the services performed by PCT under the agreement are owned solely and exclusively by and assigned to us. Through December 31, 2013, we have entered into statements of work with PCT aggregating $2.7 million.

In February 2013, we entered into a Master Contract Services Agreement with WuXi AppTec, pursuant to which WuXi AppTec 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 from time to time. Through December 31, 2013, we have entered into statements of work with WuXi AppTec aggregating $0.9 million.

Intellectual Property

General

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 advisors, 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, advisors 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.

TSO

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 comprised 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.

CNDO-109

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 natural killer 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 natural killer 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.

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.

We expect TSO, if approved for the treatment of CD, 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 IBD, UC and CD, and several other products. TSO, if developed and approved for the treatment of 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.

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.

Manufacturing

As of March 2014, we do not own or operate manufacturing facilities for the production of TSO or CNDO-109. We do not plan to develop our own manufacturing operations in the foreseeable future for CNDO-109. We currently have a five-year property lease in Woburn, MA for space, which can be developed to establish a TSO manufacturing facility. However, based upon TRUST-I results in October 2013, we are currently evaluating our TSO manufacturing plans.

We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredient and finished products for our preclinical and clinical trials. Pursuant to the Ovamed Supply Agreement, we are required to purchase from Ovamed and Ovamed has agreed to manufacture and supply us with Phase 2 clinical requirements of TSO at pre-determined prices. We may purchase at least a portion of our Phase 3 supplies of TSO from Ovamed. PCT provides us with clinical services and supplies for CNDO-109. We do not have a contractual arrangement for the manufacture of commercial supplies of CNDO-109.

We, Ovamed and our third party suppliers are required to comply with applicable FDA manufacturing requirements contained in the FDA's current good manufacturing practice standards, or cGMP, regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved New Drug Application "NDA"/Biological License Application "BLA", including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

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 United States 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 or other applicable regulations;
- Submission to the FDA of an 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 good laboratory practices. 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 US 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 US, 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 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 post-marketing testing, known as 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 U.S. Patent and Trademark Office 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. 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, 2013, we had 14 full time employees.

Executive Officers

The following table sets forth certain information about our executive officers as of December 31, 2013.

Name	Age	Position
Lindsay A. Rosenwald, M.D.	58	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.	61	Senior Vice President, Biologics Operations
Kevin Horgan, M.D.	54	Chief Medical Officer

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, LLC, 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 been instrumental 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.

Kevin Horgan, M.D. served as our Chief Medical Officer from November 2013 until he separated from our Company in January 2014. Prior to joining Coronado, he was at Soligenix, Inc. as Senior Vice President and Chief Medical Officer since 2011. From 2008 to 2011, Dr. Horgan was Head of Internal Medicine at GE Healthcare, a part of General Electric Co. From 2006 to 2008, he was Vice President of Clinical Immunology at Janssen Biotech, Inc. (formerly Centocor Ortho Biotech, Inc.), where he designed and conducted gastroenterology clinical studies for new compounds and indications including REMICADE® (infliximab) and STELARA® (ustekinumab). From 1997 to 2006, Dr. Horgan was Senior Director of Clinical Research at Merck & Co., Inc., where he led the development of the first neurokinin-1 receptor antagonist, EMEND® (aprepitant), to be approved for the prevention of chemotherapy-induced nausea and vomiting. From 1995 to 1997, Dr. Horgan was the Director of the IBD Center at the University of California, Los Angeles ("UCLA"). Dr. Horgan graduated in medicine from University College Cork, Ireland and completed his training in internal medicine at the Queen Elizabeth Hospital, Birmingham, United Kingdom and the Johns Hopkins Hospital, Baltimore, Maryland. He did an immunology research fellowship with the National Cancer Institute in Bethesda, Maryland and completed a fellowship in gastroenterology at UCLA.

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, NC 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 Coronado and other companies that file materials with the SEC electronically. Copies of Coronado's 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 plan to identify, evaluate and potentially in-license, acquire or invest in pharmaceutical and biotechnology products, technologies and/or companies. 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 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.

As we 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 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 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.

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 business.

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.

Risks Related to Our Business and Industry

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

We remain a development stage biopharmaceutical company. To date, we have engaged primarily in research and development activities and have not generated any revenues from product sales. We have incurred significant net losses since our inception. As of December 31, 2013, we had an accumulated deficit of approximately $121.3 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 to date have been limited to organizing and staffing our company, acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of our product candidates. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to commercialize our current product candidates and develop future product candidates, if any, 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.

Until we have fully analyzed the TRUST-I trial data, have received, reviewed and fully analyzed the results of the TRUST-II trial, and have determined the development path, if any, for TSO, we cannot give any assurances as to 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, University of Iowa Research Foundation, or UIRF, in exchange for annual and milestone payments, patent cost reimbursement, royalties based on sales and diligence obligations. Our rights to TSO are, therefore, also subject to Ovamed's performance of its obligations to UIRF, any breach of which we may be required to remedy in order to preserve our rights.

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

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

Pharmaceutical development has inherent risk. We will be required to demonstrate through well-controlled clinical trials that our 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 a New Drug Application, an NDA, or Biologics License Application, or BLA, to the FDA and even fewer are approved for commercialization.

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

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

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

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

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

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

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

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

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

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

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

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

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

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial 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.

Our potential postponement in establishing the manufacturing portion of our Woburn, M.A. facility to produce clinical supplies and commercial supplies of TSO and our dependence on third party suppliers or our inability to successfully produce TSO could adversely impact our business.

We are evaluating the future use of our Woburn MA facility and may ultimately postpone manufacturing in the United States. As such, we continue to rely exclusively on Ovamed to supply us with our requirements of TSO, which it is currently producing at only one facility in Germany and where it also is producing product for third parties, including Falk. If Ovamed becomes unable or unwilling to deliver sufficient quantities of TSO to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there would be a significant interruption of our TSO supply, which may adversely affect clinical development and potential commercialization of the product. In the event that the FDA or such other agencies determine that we, Ovamed or 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, we or any other contract manufacturer who supply Ovamed or us cannot successfully manufacture material that conforms to our specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for TSO. We, Ovamed and our third-party suppliers are and will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable .agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of our or Ovamed's facilities or operations or of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

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

We or Ovamed may not have the resources or capacity to commercially manufacture TSO, if approved, and 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 Progenitor Cell Therapy, or PCT, and other third parties to manufacture our preclinical and clinical pharmaceutical supplies of CNDO-109 and expect to continue to rely on these third parties to produce commercial supplies of CNDO-109, and our dependence on third party suppliers could adversely impact our business.

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

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

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

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

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

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

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

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

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

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

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

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

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- acceptance of the product by the target population;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;

- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

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

We may 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 or costly.

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

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

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

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

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

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

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

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

We also intend to rely on our ability to obtain and maintain a regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is currently 12 years from the date of marketing approval, 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, United States patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, and includes a number of significant changes to United States patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The U.S. Patent and Trademark Office implemented the America Invents Act on March 16, 2013, and it remains to be seen how the judicial system and the U.S. Patent and Trademark Office will interpret and enforce these new laws. Accordingly, it is not clear what impact, if any, the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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

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

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign our products or processes to avoid infringement;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;

- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or

- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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

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

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

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

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

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

We are a development stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses in all periods since our inception in September 2006, including losses of approximately $36.4 million, $27.6 million and $37.2 million for the years ended December 31, 2011, 2012 and 2013, respectively. At December 31, 2013, we had an accumulated deficit of approximately $121.3 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")."). 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 would force us to delay, curtail or eliminate one or more of our research and development programs, commercialization efforts, and our growth strategy.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2011, 2012 and 2013 we incurred research and development expenses of approximately $8.6 million, $17.5 million and $25.7 million, respectively. Since our inception in 2006, we incurred research and development expenses of approximately $67.7 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, 2013, will enable us to continue to fund operations in the normal course of business for at least the next 12 months. However, we will continue to depend on funding our operations from our existing cash for the foreseeable future. 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 research and development activities, expenditures and growth strategy, increased expenses or other events may affect our need for additional capital in the future and may require us to seek additional funding sooner than anticipated.

Our ability to successfully raise sufficient funds through the sale of debt or equity securities or from debt financing from lenders when needed is subject to many risks and uncertainties and, even if we are successful, future equity issuances would result in dilution to our existing stockholders.

We have based this estimation on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration or licensing arrangements. We currently have no agreements to obtain any additional financing and we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

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, 2013, Lindsay A. Rosenwald, M.D., our Chairman, President and Chief Executive Officer, beneficially owned approximately 14.1% of our issued and outstanding capital stock. At February 20, 2014, Michael S. Weiss, our Executive Vice Chairman, Strategic Development, beneficially owned approximately 15.0% 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 Weis, 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 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 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 and the acquisition of potential new product candidates;
- 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 39.7 million outstanding shares of common stock as of December 31, 2013, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, or an effective registration statement. In addition, in September 2012, we filed a shelf registration statement on Form S-3, pursuant to which we may sell up to $75 million of our equity securities over the next three years. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock. We sold 3,361 shares of our common stock resulting in net proceeds to us of $19,000 in 2012 and we sold 10,558,422 shares of our common stock resulting in net proceeds to us of $89.4 million pursuant to this Form S-3 in 2013.

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

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

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 for approximately 3,200 square feet of space providing for rental payments of approximately $94,000 per year. Total rent expense for the term of this lease will approximate $470,000. The Company took occupancy of this space in October 2012.

On December 2012, the Company 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 the Company has not yet taken occupancy of the space.

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. Total rent expense for the term of this lease will be approximately $366,000. The Company commenced occupancy of this space in May 2013.

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 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 bid prices per share of our common stock for each full quarterly period within the two most recent fiscal years.

	2013		2012	
	High	Low	High	Low
First quarter	$ 9.72	$ 4.84	$ 9.52	$ 5.00
Second quarter	$ 12.00	$ 7.55	$ 8.50	$ 4.93
Third quarter	$ 10.05	$ 6.82	$ 6.92	$ 5.20
Fourth quarter	$ 8.30	$ 1.27	$ 5.97	$ 4.36

Holders of Record

As of March 12, 2014, there were approximately 117 holders of record of our common stock.

Repurchases

None.

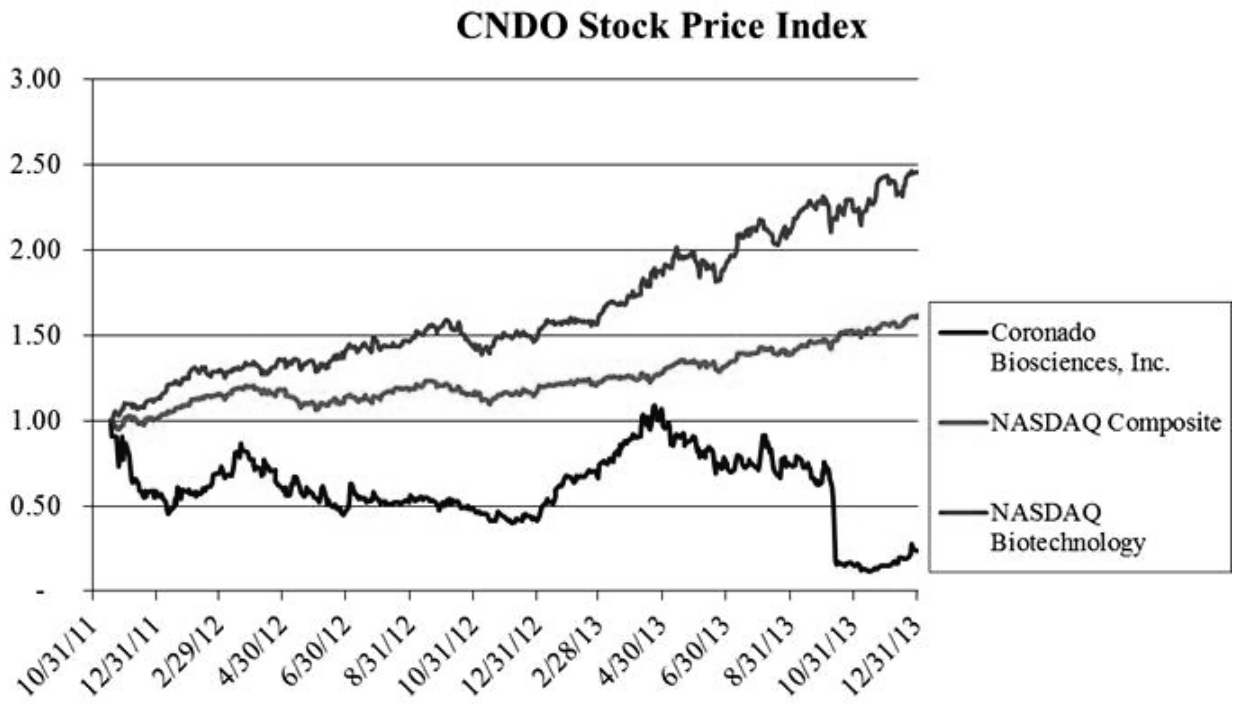
Dividends

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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of our other filings under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), except to the extent we specifically incorporate it by reference into such filing.

This chart 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 chart is indexed based on the stock price on November 30, 2011.

Sales of Unregistered Securities

On December 19, 2013, the Company issued to each of Lindsay A. Rosenwald and Michael S. Weiss 1,979,346 shares of restricted common stock of our Company for services to be rendered to our Company. These issuances, which were made pursuant to restricted stock issuance agreements and under Section 4(2) of the Securities Act, provides that one third of the shares will vest when our Company achieves market capitalization of two, three and four times our market capitalization on the date of grant, but in no event earlier than three, four and five years following the date of grant, respectively.

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.

	For the Years Ended December 31,				
	2013	2012	2011	2010	2009
(In thousands except per share amounts)					
Operating expenses:					
Research and development	$ 25,682	$ 17,468	$ 8,583	$ 8,341	$ 2,270
General and administrative	10,098	8,665	5,755	900	343
In-process research and development	—	1,043	20,706	—	—
Loss from operations	(35,780)	(27,176)	(35,044)	(9,241)	(2,613)
Interest income	545	236	165	61	—
Interest expense	(1,923)	(670)	(74)	(1,535)	(1,053)
Other income	—	—	—	733	—
Warrant expense	—	—	(1,407)	—	—
Net loss	(37,158)	(27,610)	(36,360)	(9,982)	(3,666)
Common Stock dividend to Series A Convertible Preferred Stockholders	—	—	(5,861)	—	—
Net loss attributed to Common Stockholders	$ (37,158)	$ (27,610)	$ (42,221)	$ (9,982)	$ (3,666)
Basic and diluted net loss per common share	$ (1.22)	$ (1.27)	$ (5.51)	$ (2.24)	$ (1.01)
Weighted average common shares outstanding—basic and diluted	30,429,743	21,654,984	7,662,984	4,453,786	3,612,769
Financial Condition:					
Cash	$ 99,521	$ 40,199	$ 23,160	$ 14,862	$ 1,510
Total assets	$ 100,582	$ 40,992	$ 23,375	$ 14,939	$ 1,687
Current liabilities	$ 11,210	$ 5,132	$ 3,493	$ 1,559	$ 11,207
Long-term liabilities	$ 8,094	$ 13,827	$ 750	$ —	$ 570
Stockholders' equity/(deficit)	$ 81,278	$ 22,033	$ 19,132	$ (15,897)	$ (10,090)

As part of our growth strategy, we plan to identify, evaluate and potentially in-license, acquire or invest in pharmaceutical and biotechnology products, technologies and/or companies. We may also from time to time consider financing existing or later-acquired products, technologies or companies through partnerships, joint ventures, direct financings, and/or public or private 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 this table may not be indicative of future financial conditions and/or results of operations.

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.

Overview

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 plan to identify, evaluate and potentially in-license, acquire or invest in pharmaceutical and biotechnology products, technologies and/or companies. We may also from time to time consider financing existing or later-acquired products, technologies or companies through partnerships, joint ventures, direct financings, and/or public or private 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.

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

- TSO, or CNDO-201, the microscopic eggs of the porcine whipworm, for the treatment of autoimmune diseases, such as Crohn's disease, or CD, ulcerative colitis, or UC, multiple sclerosis, or MS, autism, psoriasis, and type 1 diabetes, or T1D; 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.

We acquired exclusive rights to TSO in January 2011 from Asphelia for an aggregate purchase price of $20.7 million, consisting of 2,525,677 shares of our Series B Convertible Preferred Stock, or Series B Shares, valued at $6.38 per share, the assumption of a promissory note due to Paramount Credit Partners, or PCP, in the aggregate principal amount of $750,000, (the "PCP Note") which was prepaid in September 2012 and the assumption of Asphelia's obligation to reimburse Ovamed for certain development costs. Of this purchase price, $3.8 million has been paid in cash, including $3.4 million to Ovamed and $0.4 million for repayment of Asphelia's debt, including $61,000 to a related party. Under the terms of a sublicense agreement with Ovamed that we acquired from Asphelia, we are required to make annual license payments to Ovamed of $250,000, reimburse patent expenses, make payments totaling up to $5.4 million, of which $3.0 million was paid, contingent upon the achievement of various milestones related to regulatory events for the first product to be approved for marketing, and make additional milestone payments, contingent upon the achievement of regulatory events related to subsequent indications for TSO. In the event that TSO is commercialized, we will be obligated to pay annual royalties based upon net sales of the product. If we sublicense TSO, we must pay Ovamed a portion of sublicense revenues we receive, if any. We have been required to purchase our clinical requirements of TSO from Ovamed at pre-determined prices.

In December 2012, we and Ovamed entered into the Second Amendment amending certain provisions of our Exclusive Sublicense Agreement and our Manufacturing and Supply Agreement, between us and Ovamed, and providing for certain additional agreements between the parties. Pursuant to the Second Amendment, our exclusive license from Ovamed in the North America, South America and Japan known as the "Coronado Territory" was amended to include an exclusive license to make and have made product containing TSO in the Coronado Territory 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, as amended, terminates 15 years from the first commercial sale of TSO 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 will be the greater of (i) a royalty on net sales of product we manufacture or (ii) a specified amount per unit, 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 10 business days following FDA approval of a Biologics License Application authorizing the manufacturing, marketing and commercial sale of product containing TSO 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 for space in Woburn, MA. However, based upon TRUST-I results in October 2013, we are currently evaluating our TSO manufacturing plans. The build out and technology transfer to the Woburn site will require an incremental investment from Coronado and will take approximately twelve months upon a decision to proceed. Ovamed agreed to assist us in establishing the Woburn facility and the Second Amendment contemplates that we and Ovamed may act as second source suppliers to each other at agreed transfer prices pursuant to a Second Source Agreement to be negotiated between the parties.

In March 2012, we signed a Collaboration Agreement with Falk and Ovamed for the development of TSO for treatment of CD. Under the Collaboration Agreement, Falk granted us exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO as a treatment for CD, including Falk's ongoing Phase 2 clinical trial, for use in the Coronado Territory. We granted Falk exclusive rights and licenses to data from our clinical trials of TSO in CD for use in Europe. Under the agreement, we agreed to pay Falk (i) a total of €5 million (approximately $6.5 million) after receipt of certain pre-clinical and clinical data, of which €2.5 million (approximately $3.4 million) was paid in 2012 and the remaining €2.5 million is expected to be paid in the first half of 2014 upon receipt of the CSR, and (ii) a royalty of 1% of net sales of TSO in North America, South America and Japan. A steering committee comprised of our representatives and representatives of Falk and Ovamed is overseeing the clinical development program of TSO as a treatment 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 treatment of CD in the United States and Europe and will share in certain pre-clinical development costs.

In February 2013, we and Freie Universität Berlin ("FU Berlin") entered into a Research Agreement to, among other things identify and evaluate secretory proteins from TSO. The duration of the project is expected to be four years, during which time the Company will pay FU Berlin a total maximum amount of approximately $853,000 in research fees, commencing February 2013 and ending January 2017. We also entered into several license agreements regarding intellectual property that may result from this research. (See Note 14 of Notes to Consolidated Financial Statements.)

In October 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 have 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, 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.

Until we have fully analyzed the TRUST-I trial data, have received, reviewed and fully analyzed the results of the TRUST-II trial, and have determined the development path, if any, for TSO, we cannot give any assurances as to the future development of TSO, the indications for which TSO could be a treatment, or the costs and timelines for any development plans.

We are continuing to evaluate the data from TRUST-I. We will use this analysis, along with the results of TRUST-II, other current data on TSO and other factors to determine our future development plans for TSO.

We acquired an exclusive worldwide license to CNDO-109 in November 2007 from University College of London Business PLC, or UCLB. In consideration for the license, we paid UCLB initial license fees totaling $0.1 million and are required to make milestone payments totaling up to $22 million upon the achievement of various milestones related to regulatory events for the first three indications. In March 2012, we recognized our $250,000 milestone obligation to UCLB related to our IND filed in February 2012 and in April 2012 we paid UCLB for this milestone. In June 2012, we were notified by the FDA that CNDO-109 was granted orphan drug designation and in September 2012, the U.S. Patent and Trademark Office issued the first U.S. patent covering CNDO-109. If CNDO-109 is commercialized, we will be obligated to pay to UCLB annual royalties based upon net sales of the product or if we sublicense CNDO-109, a portion of sublicensing revenues we receive, if any.

In June 2012, we completed an underwritten public offering of 5,750,000 shares of our common stock, including 750,000 shares subject to an over-allotment option exercised by the underwriters, at a price of $5.00 per share for proceeds, net of underwriting commissions and other offering expenses, of approximately $26.4 million. In August 2012, we received net proceeds of $14.7 million from a $15 million term loan with Hercules Technology Growth Capital, Inc. (the "Hercules Note"), which we subsequently repaid and terminated in February 2014. (See Note 17 of Notes to Consolidated Financial Statements.)

In September 2012, we filed a shelf registration statement on Form S-3 (the "2012 Form S-3") pursuant to which we could sell up to a total of $75.0 million of our 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, we entered into a new $45.0 million At Market Issuance Sales Agreement with MLV whereby we 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, we filed a shelf registration statement on Form S-3 (the "2013 Form S-3"), which was declared effective on August 19, 2013. We may sell up to $200.0 million of our equity securities under the 2013 Form S-3. In connection with the 2013 Form S-3, we amended our 2013 ATM with MLV such that we may offer and sell additional shares of our 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, we will pay directly to MLV fees of up to 3% of the gross proceeds of the ATMs then in effect. In the year ended December 31, 2013, we sold 10,558,422 shares of Common Stock under the ATMs and received net proceeds of $89.4 million.

On December 28, 2012, the Company's board of directors appointed current director Dr. Harlan F. Weisman, as Chairman and Chief Executive Officer. At that time, the Company's Executive Chairman, Dr. Glenn L. Cooper, resigned his position as Executive Chairman and as a director of the Company. In addition, on December 28, 2012, Dr. Bobby W. Sandage, Jr.'s status as Chief Executive Officer and President of the Company changed to President of the Company. Dr. Sandage remained a member of the board of directors. In April 2013, Dr. Bobby W. Sandage, Jr. resigned from his position as president of our company and as a member of the board of directors. (See Note 15 of Notes to Consolidated Financial Statements.)

On November 5, 2013, the Company appointed Kevin Horgan, M.D. as its Chief Medical Officer and on January 28, 2014, Dr. Horgan was separated from service with the our Company. The Company also announced on November 6, 2013 a reduction in force affecting Mr. Noah Beerman, its Executive Vice President and Chief Operating Officer, Mr. Dale Ritter, its Senior Vice President, Finance and Chief Accounting Officer and Dr. Karin Hehenberger, its Executive Vice President of Scientific Affairs. (See Note 15 of Notes to Consolidated Financial Statements.)

On December 19, 2013, the Company appointed Lindsay A. Rosenwald, as Chairman, President and Chief Executive Officer. At that time, Harlan F. Weisman, resigned his position as Chairman and Chief Executive Office and as a director of the Company. In addition, on December 19, 2013, Mr. Michael S. Weiss joined the Company as Co-Vice Chairman of the board of directors and, on February 20, 2014, was appointed Executive Vice Chairman, Strategic Development. (See Note 15 of Notes to Consolidated Financial Statements.)

On December 24, 2013 Michael Rogers, a member of our Board of Directors and Chairman of the Audit Committee, informed us that he was resigning as director effective December 26, 2013.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are 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 accrued expenses and stock-based compensation. 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, 2013 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:

- Fair Value of our common stock. When our stock was not publicly traded, we estimated the fair value of common stock as discussed in "Common Stock Valuations Prior to Becoming a Publicly Traded Company" below. Since November 17, 2011, we have 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, 2011, 2012, and 2013, stock-based compensation expense was $1.5 million, $3.6 million, and $5.9 million, respectively. As of December 31, 2013, we had approximately $3.4 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 1.3 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 in 2013. These awards vest upon both the achievement of certain market capitalization goals and continued service. 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 agreement of 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. Coronado's 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 year ended December 31, 2013, compensation expense recognized associated with these market condition awards was $66,000 using a graded vesting expense attribution model and unrecognized expense was approximately $7.6 million which we expect to recognize over a weighted-average period of approximately 5.0 years. No expense was recorded in 2011 and 2012.

Common Stock Valuations Prior to Becoming a Publicly Traded Company

Prior to our becoming a publicly-traded company on November 17, 2011, the fair value of the common stock underlying our stock options, common stock warrants and restricted stock was determined by our board of directors, which intended all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. However, certain options granted on October 5, 2010 were granted with an exercise price that was below the fair value of our common stock as subsequently determined by an independent valuation as of that date. All other options previously granted or to be granted in the future are granted at the determined grant date fair value. The valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants, or AICPA, Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Guidelines. The assumptions we use in the valuation model are based on future expectations combined with management judgment. In the absence of a public trading market, our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option, restricted stock and warrant grant, including the following factors:

- arm's length private transactions involving our preferred stock, including the sale of our Series A Convertible Preferred Stock, or Series A Shares, at $8.39 per share in 2010 and our Series C Convertible Preferred Stock, or Series C Shares, at $5.59 per share in 2011;
- independent valuations performed by knowledgeable experts in the field;
- our operating and financial performance;
- market conditions;
- developmental milestones achieved;
- business risks; and
- management and board experience.

In valuing our common stock, we have used a variety of methodologies that have evolved as the life cycle of our company has progressed. For the underlying valuations of our common stock in periods prior to December 31, 2009, given the early stage of our company and its development programs, we used a cost approach to estimate the fair value of our common stock. The cost approach is based on the premise that an investor would pay no more for an asset than its replacement or reproduction cost. The cost to replace the asset would include the cost of constructing a similar asset of equivalent utility at prices applicable at the time of the valuation analysis. Under this methodology, a valuation analysis is performed for a company's identified fixed, financial, intangible and other assets. The derived aggregate fair value of the assets is then netted against the estimated fair value of all existing and potential liabilities, resulting in an indication of the fair value of total equity. This approach was considered an appropriate indication of value as the programs were still in early stages of the development cycle.

As our business and programs evolved, beginning in 2010, we migrated away from the cost approach to a market approach to incorporate the indication of value established through our development efforts and reflected in our Series A Share issuances during 2010. Under this approach, the business enterprise value was established based on the contemporaneous equity offerings. Pursuant to the AICPA Guidelines, an option pricing method was used to value the shares using a contingent claims analysis, which applies a series of call options whose inputs reflect the liquidation preferences and conversion behavior of the different classes of equity. The value of our common stock was then derived by analyzing the fair value of these options. After the equity value of the business enterprise was determined, the total equity value of any equity instruments such as preferred stock, stock options, restricted stock and warrants outstanding and the concluded common stock value on a converted basis is allocated. Next, the option pricing method was used to allocate the residual equity value (inclusive of any infusion of cash from in-the-money options and warrants) to our common stock. Since our shares were not publicly traded, a discount for lack of marketability was applied. This lack of marketability discount was estimated to be 10% prior to becoming a publicly-traded company. A theoretical put option model was used to capture the cost to ensure stock could be sold at the price prevailing at the valuation date after the time required to finding a market, or the time until an expected liquidity event. The put option model considers the expected time to a liquidity event, estimated volatility based on Peer Company data, risk free interest rates and management judgment. The ultimate fair values of our common stock were used as an input in determining the fair value of the warrants, restricted stock and stock options at various periods of time. As our development programs continue we expect to incur an increase in research and development expenses.

Results of Operations

General

To date, we have not generated any revenues from operations and, at December 31, 2013, we had an accumulated deficit of $121.3 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 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 is central to our business. For the years ended December 31, 2011, 2012 and 2013 research and development expenses were $8.6 million, $17.5 million and $25.7 million, respectively, and such expenses were $67.7 million for the period from inception (June 28, 2006) to December 31, 2013. Noncash, stock-based compensation expense included in research and development in 2013 and from inception through 2013 was $3.0 million and $7.7 million, respectively. Research and development expenses consist primarily of:

- employee-related expenses, which include salaries and benefits, and rent expense;
- non cash 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 significant expenses related to our research and development activities for the foreseeable future as we develop our existing product candidates and any 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, we expect that our research and development expenses will 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. From inception through December 31, 2013, direct, external development costs incurred for our TSO product development program were $26.0 million, including $2.7 million, $10.9 million and $12.2 million for the years ended December 31, 2011, 2012 and 2013, respectively. Excluded from these costs is $21.7 million of in-process research and development costs, consisting of $20.7 million related to our acquisition of certain rights to TSO in 2011 and $1.0 million related to our domestic manufacturing rights for TSO. From inception through December 31, 2013, direct, external development costs incurred for our CNDO–109 product development program were $8.4 million, including $1.9 million, $1.9 million and $2.2 million, for the years ended December 31, 2011, 2012 and 2013, respectively. Our results of operations for the year ended December 31, 2011 include direct, external development costs incurred in connection with two product development programs that have been discontinued. From inception through December 31, 2013, such expenses totaled $5.2 million. No costs were incurred for these programs in 2012 and 2013.

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. From inception to December 31, 2013, general and administrative expenses were $26.4 million, including $5.8 million, $8.7 million, and $10.1 million for the years ended December 31, 2011, 2012 and 2013 respectively. Non cash, stock-based compensation expense included in general and administrative in 2013 and from inception through 2013, was $2.9 million and $5.7 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; 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, 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 Agreement with Ovamed; while in 2012, we also incurred a $3.3 million of milestone-related charges in connection with our 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. We expect to incur expenses related to our research and development efforts going forward with existing products as well as related to new products.

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 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 in 2013, the $0.5 million payable in December 2014 is recorded in accrued expenses and $0.7 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.

Comparison of Years Ended December 31, 2012 and 2011

	For the year ended December 31,		Variance	
	2012	2011	$	%
Operating expenses:				
Research and development	$ 17,468	$ 8,583	$ 8,885	104 %
General and administrative	8,665	5,755	2,910	51 %
In-process research and development	1,043	20,706	(19,663)	(95)%
Loss from operations	(27,176)	(35,044)	(7,868)	(22)%
Interest income	236	165	71	43 %
Interest expense	(670)	(74)	596	805 %
Warrant expense	—	(1,407)	(1,407)	NM
Net loss	$ (27,610)	$ (36,360)	$ (8,750)	(24)%

NM–Not meaningful

Research and development expenses increased $8.9 million, or 104%, from the year ended December 31, 2011 to the year ended December 31, 2012. This increase was primarily due to $8.3 million of increased external development costs related to TSO. In 2012, we incurred $4.0 million of expense related to our Phase 2 study for TSO. We also incurred an increase in contractual milestone-related costs in 2012. In 2011 we incurred a milestone-related charge of $1.5 million related to the filing of an IND for TSO, and in 2012 we incurred $3.3 million of milestone-related charges in connection with our agreement with Falk and a $0.2 million milestone-related charge pursuant to our agreement with Ovamed. Additionally, we purchased $2.0 million of TSO clinical supply from Ovamed. Personnel costs increased $0.4 million in 2012, primarily due to increased staffing. In addition, 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 were essentially unchanged. We expect our research and development expenses to increase in future quarters as our clinical programs for TSO continue.

General and administrative expenses increased $2.9 million, or 51%, from the year ended December 31, 2011 to the year ended December 31, 2012, reflecting a substantial increase in the level of our business activity during 2012, our first full year as a public company. The increase in general and administrative expenses to support these activities consisted primarily of a $1.7 million increase in stock compensation expense, including $0.3 million related to the modification of options issued to certain of our executive officers (See Note 15 of Notes to the Consolidated Financial Statements), $0.3 million related to warrants issued to consultants and $1.0 million related to options granted to new employees and directors. Personnel-related costs increased $1.0 million, primarily due to the addition of our new Chief Operating Officer in September 2011, and Chief Financial Officer in February 2012.

In January 2011, we acquired a sublicense for TSO from Asphelia, entered into related agreements for TSO and assumed certain liabilities of Asphelia. In connection with these transactions, we issued 2,525,677 Series B Shares valued at $6.38 per share, assumed the PCP Note, in the principal amount of $750,000 and made cash payments totaling $3.8 million, including $3.4 million to Ovamed and $0.4 million for repayment of Asphelia' s debt, including a $61,000 payment to a related party. The total consideration paid in connection with the acquisition of our rights to TSO from Asphelia was $20.7 million, which was recorded as in-process research and development expense in 2011. In 2012, we acquired from Ovamed manufacturing rights for TSO in 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. This liability is included in other long-term liabilities at December 31, 2012. Payments will be made in three equal annual installments of $500,000, commencing in December 2014.

Interest expense of $0.7 million in 2012 included $0.6 million related to the Hercules Note and the remaining $0.1 million related to the PCP Note, which was paid in full in September 2012. In 2011, we recognized interest expense of $74,000 related to the PCP Note.

The increase in interest income in 2012 compared to the same period last year was primarily due to higher cash balances.

Warrant expense of $1,407,000 in 2011 was a noncash expense related to the marking-to-market of the warrants for Series C Shares issued to the placement agent for its services in connection with the issuance and sale of the Series C Shares. A warrant liability of $1,286,000 was established at June 30, 2011 upon the issuance of the warrants. This liability was valued for a final time at $2,693,000 on November 15, 2011 upon the effectiveness of our resale registration statement on Form S-1. The expense represents the change in value from June 30, 2011 to November 15, 2011. This liability was reclassified to equity upon effectiveness of the Form S-1.

Liquidity and Capital Resources

To date, we have funded our operations through the sale of debt and equity securities aggregating $180.6 million of net proceeds. At December 31, 2013, we had cash of $99.5 million. In 2013, we sold 10,558,422 shares of Common Stock pursuant to our 2012 and 2013 ATMs and received net proceeds of $89.4 million. As of December 31, 2013 and 2012, no shares of our preferred stock were outstanding.

In June 2012, we completed an underwritten public offering of 5,750,000 shares of our common stock, including 750,000 shares subject to an over-allotment option exercised by the underwriters, at a price of $5.00 per share, for proceeds, net of underwriting commissions and other offering expenses, of approximately $26.4 million. In August 2012, we received net proceeds of $14.7 million from a $15.0 million term loan from Hercules. In October 2012, our registration statement filed in September 2012 on Form S-3 registering to sell, from time to time in one or more offerings, any combination of common stock, preferred stock, warrants, or units having a maximum aggregate offering price of $75.0 million, was declared effective. On October 5, 2012, we entered into an ATM with MLV, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $30.0 million from time to time through MLV, as our sales agent. The offering pursuant to the ATM will terminate upon the earlier of (i) October 5, 2015; (ii) the sale of all shares of common stock subject to the ATM, or (iii) termination of the ATM. The ATM may be terminated by either party at any time upon 10 days' notice to the other party, or by MLV at any time in certain circumstances, including upon the occurrence of a material adverse change in our company. In 2012, we sold 3,361 shares of common stock for $19,000 of net proceeds pursuant to the Sales Agreement.

In July 2013, we filed the 2013 Form S-3, which was declared effective on August 19, 2013. Under the Amended 2013 ATM established in connection therewith, 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 Amended 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 capital stock from 65,000,000 shares to 115,000,000 shares and to increase the number of authorized shares of Common Stock from 50,000,000 to 100,000,000. In February 2014, the Company repaid the Hercules Loan Agreement in full and entered into a new Promissory Note with Israel Discount Bank of New York in the amount of $15.0 million (see Note 17 of Notes to Consolidated Financial Statements).

We will require additional financing to fully develop, and prepare regulatory filings and obtain regulatory approvals for our existing product candidates (and potentially new product candidates), fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for our potential products (and potentially new product candidates), 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 would 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, 2013, 2012 and 2011

	For the Year Ended December 31,		
(In thousands)	**2013**	**2012**	**2011**
Statement of Cash Flows Data:			
Total cash provided by (used in):			
Operating activities	$ (29,646)	$ (23,194)	$ (10,952)
Investing activities	(188)	(279)	(3,843)
Financing activities	89,156	40,512	23,093
Increase in cash and cash equivalents	$ 59,322	$ 17,039	$ 8,298

Operating Activities

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 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.

Net cash used in operating activities increased $12.2 million from the year ended December 31, 2011 to the year ended December 31, 2012. Net loss decreased $8.8 million and stock-based compensation increased $2.2 million due to an increase in the number of stock options and warrants outstanding and the impact of our higher stock price on the value of options and warrants held by non-employees. Offsetting these increases to cash from operations was a $19.7 million decrease in the amount of acquired in-process research and development from the year ended December 31, 2011 to the year ended December 31, 2012. This decrease was due to our recognition in 2011 of a $20.7 million noncash expense for in-process research and development in connection with our acquisition of certain rights related to TSO. In 2012, we recognized a $1.0 million noncash expense in connection with our acquisition of TSO manufacturing rights from Ovamed. A $0.3 million decrease in accounts payable and accrued expenses and the absence of the $1.4 million increase in the fair value of the Series C warrant liability in 2011 were additional factors leading to the increase in cash used in operations.

Investing Activities

Net cash used in investing activities was $0.2 million in 2013 and consisted primarily of payments made to build-out the office area of our manufacturing facility.

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.

Net cash used in investing activities was $3.8 million in 2011 and consisted solely of cash payments related to our acquisition of certain rights related to TSO from Asphelia.

Financing Activities

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 ATM, 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 million term loan from Hercules, offset by our payment of $750,000 in satisfaction of our obligations under the PCP Note.

Net cash provided by financing activities in the year ended December 31, 2011 of $23.1 million consisted of $22.9 million of net proceeds from our issuance of the Series C Shares and $193,000 received upon the exercise of employee stock options.

Contingent Contractual Payments

The following table summarizes our contractual obligations as of December 31, 2013, 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)	$ 15,600	$ 7,305	$ 8,295	$ —	$ —
Operating leases (2)	1,231	351	858	22	—
Annual license fees (3)	13,918	4,468	2,950	500	6,000
Purchase and other obligations	8,437	4,947	3,490	—	—
Total	$ 39,186	$ 17,071	$ 15,593	$ 522	$ 6,000

(1) Relates to Hercules Note.
(2) Relates to New York, NY, Burlington, MA and Woburn, MA leases.
(3) Annual sublicense fees are projected through 2025 and include payments to Ovamed, Falk and UCLB.

As of December 31, 2013, approximately $1.1 million of contingent contractual payments are reflected in accrued expenses and in purchase and other obligations in the table above.

On February 13, 2014, we executed a Promissory Note with Israel Discount Bank of New York in the amount of $15.0 million. Our obligations under the note are collateralized by a secure interest in, a general lien upon, and a right of set-off against our money market account of $15.0 million. Also on February 13, 2104, we used a portion of the proceeds from this note to repay our Hercules Note in full (see Note 17 of Notes to Consolidated Financial Statements).

Our purchase and other obligations are primarily associated with our clinical trials, including approximately $2.1 million for our Phase 2 trial evaluating TSO as a treatment for CD, including $0.5 million of product supply from Ovamed and approximately $5.1 million for services associated with our planned Phase 1/2 CNDO-109 trial.

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.

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.

Pursuant to the Second Amendment and Agreement, in December 2012, 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 will 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 December 2012, we signed the Manufacturing Agreement with Ovamed, which 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 commencing December 2014, which is included in annual license fees.

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 held no marketable securities at December 31, 2013 and 2012. The Hercules Note, which we repaid and terminated in February 2014, 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%. To the extent the prevailing prime rate had exceeded 3.25%, the Company would have paid a higher rate of interest on any then-outstanding principal balance.

Net Operating Loss Tax Carry-Forwards

As of December 31, 2013, we had federal net operating loss carryforwards of approximately $87.6 million to offset future federal income taxes which expire beginning in 2026 and state net operating loss carryforwards of $35.2 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, 2013 and 2012, 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 $2.7 million of the federal net operating loss carryforward and $1.5 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, 2013, 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, 2013. 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 (1992)*.

Based on our assessment, our management has concluded that, as of December 31, 2013, our internal controls over financial reporting were effective based upon those criteria.

The effectiveness of our internal controls over financial reporting as of December 31, 2013 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Changes in Internal Controls over Financial Reporting.

Effective November 5, 2013, we terminated Dale Ritter, Senior Vice President, Finance and Chief Accounting Officer, in connection with our effort to lower operating expenses and realign our organization to work more efficiently given the results of the Phase 2 TRUST-I clinical trial for TSO in CD. As a result of this termination, the Company engaged a third party accounting and advisory firm to: (1) provide technical accounting research and guidance related to existing or newly applicable authoritative pronouncements; (2) provide assistance with drafting financial statements and the applicable disclosures; and (3) assist in the valuation of certain stock based compensation awards.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item concerning our directors is incorporated by reference from the section captioned "Election of Directors" and "Corporate Governance Matters" contained in our proxy statement related to the 2014 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2014 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.

Our board of directors has determined that all of the members of the Audit Committee, Messrs. Barrett (Chairman) and Lobell, and Dr. Harvey are independent within the meaning of the NASDAQ Stock Market listing rules and meet the additional test for independence for audit committee members imposed by Securities and Exchange Commission regulation and the NASDAQ Stock Market listing rules. Our board has also determined that the Mr. Barrett is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K.

We have adopted a code of ethics relating to the conduct of our business by all of our employees, officers and directors. The Code of Ethics is available under the Investors-Governance-Governance Documents section of our website at *www.coronadobiosciences.com*.

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

The information required by this Item concerning compliance with Section 16(a) of the United States Securities Exchange Act of 1934, as amended, is incorporated by reference from the section of the proxy statement captioned "Section 16(a) Beneficial Ownership Reporting Compliance."

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to the information under the sections captioned "Compensation Committee Report," "Executive Compensation and Other Matters," "Compensation Discussion and Analysis," "Summary Compensation Table," "Grants of Plan-Based Awards," "Outstanding Equity Awards at 2013 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.

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, 2013 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	3,117,777	$ 4.58	966,720
Equity compensation plans not approved by stockholders	711,895	$ 2.10	—
Total	3,829,672		966,720

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.

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.

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.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements.

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

(b) Exhibits.

Exhibit Number	Exhibit Title	Incorporated by Reference (Unless Otherwise Indicated)			
		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.	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
3.6	Amended and Restated Bylaws of the Registrant.	10-12G	000-54469	3.6	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, of the Registrant.	—	—	3.8	Filed herewith
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, 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

10.20	Employment Agreement, dated as of April 1, 2011, by and among the Registrant and Glenn L. Cooper. M.D.#	10-12G	000-54469	10.20	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
10.22	Separation Agreement, dated June 3, 2011, by and between the Registrant and Gary G. Gemignani.#	10-12G	000-54469	10.22	July 15, 2011
10.23	Separation Agreement, dated December 2, 2010, by and between the Registrant and Raymond J. Tesi, M.D.#	10-12G	000-54469	10.23	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	July 15, 2011
10.28	Consulting Agreements between the Registrant and each of Mark Lowdell, Ph.D. and UCL Consultants Limited.	10-12G	000-54469	10.28	July 15, 2011
10.29	10% Senior Promissory Note, as amended, issued by Asphelia Pharmaceuticals, Inc. to Paramount Credit Partners, LLC.	10-12G	000-54469	10.29	July 15, 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
10.31	Consulting Agreement, as of September 27, 2011, by and between the Registrant and Joel Weinstock, M.D.#	S-1/A	333-177041	10.31	October 7, 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.	S-1/A	333-177041	10.34	October 7, 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 Coronado Biosciences, Inc. and Freie Universitat Berlin.	10-Q	—	10.47	May 9, 2013
10.48	License and Sublicense Agreement, dated February 22, 2013, by and between Coronado Biosciences, Inc. 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 Coronado Biosciences, Inc. and Kevin Horgan, M.D.#	8-K	—	10.52	November 6, 2013
10.53	Promissory Note dated as of February 13, 2014, in favor of Israel Discount Bank of New York.	8-K	—	10.53	February 18, 2014

10.54	Assignment and Pledge of Money Market Account dated as of February 13, 2014 in favor of Israel Discount Bank of New York.	8-K	—	10.54	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 24, 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 24, 2014
10.57	Restricted Stock Issuance Agreement dated as of December 19, 2013, by and between the Registrant and Michael S. Weiss.	—	—	—	Filed herewith
10.58	Restricted Stock Issuance Agreement dated as of December 19, 2013, by and between the Registrant and Lindsay A. Rosenwald, MD.	—	—	—	Filed herewith
10.59	Confidential Separation and Release Agreement dated as of December 22, 2013, by and between the Registrant and Harlan F. Weisman, MD.#	—	—	—	Filed herewith
14.1	Code of Ethics of Coronado Biosciences, Inc. applicable to Directors, Officers and Employees.	S-1	333-177041	14.1	September 28, 2011
21.1	Subsidiaries of the Registrant.	—	—	—	Filed herewith
23.1	Consent of PricewaterhouseCoopers LLP, 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.	—	—	—	Furnished herewith
101.SCH	XBRL Taxonomy Extension Schema Document.	—	—	—	Furnished herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Furnished herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Furnished herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Furnished herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Furnished 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.

[This page intentionally left blank.]

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
(a development stage enterprise)

CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in convertible preferred stock and stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Coronado Biosciences, Inc. and its subsidiaries (a development stage enterprise) at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013, and, cumulatively, for the period from June 28, 2006 (date of inception) to December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits (which were integrated audits in 2013 and 2012). 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 14, 2014

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
(A development stage enterprise)
Consolidated Balance Sheets
($ in thousands except for share amounts)

	December 31, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash	$ 99,521	$ 40,199
Prepaid and other current assets	510	393
Total current assets	100,031	40,592
Property & equipment, net	447	51
Other assets	104	349
Total Assets	$ 100,582	$ 40,992
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 468	$ 1,029
Interest payable	109	119
Accrued expenses	4,430	2,185
Current portion of note payable	6,203	1,799
Total current liabilities	11,210	5,132
Note payable	7,017	12,386
Other long-term liabilities	1,077	1,441
Total Liabilities	19,304	18,959
Commitments and Contingencies (Note 6)		
Stockholders' Equity:		
Convertible Preferred stock, $.001 par value, 129,767 and 584,390 Series C shares authorized, 0 shares issued and outstanding as of December 31, 2013 and 2012, respectively	—	—
Common stock, $.001 par value, 100,000,000 and 50,000,000 shares authorized, 39,652,950 and 24,400,754 shares issued and outstanding as of December 31, 2013 and 2012, respectively	40	24
Additional paid-in capital	202,580	106,193
Deficit accumulated during development stage	(121,342)	(84,184)
Total Stockholders' Equity	81,278	22,033
Total Liabilities and Stockholders' Equity	$ 100,582	$ 40,992

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

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

	For the year ended December 31,			Period from June 28, 2006 (Date of Inception) to December 31,
	2013	2012	2011	2013
Operating expenses:				
Research and development	$ 25,682	$ 17,468	$ 8,583	$ 67,691
General and administrative	10,098	8,665	5,755	26,377
In-process research and development	—	1,043	20,706	21,749
Loss from operations	(35,780)	(27,176)	(35,044)	(115,817)
Interest income	545	236	165	1,025
Interest expense	(1,923)	(670)	(74)	(5,876)
Other income	—	—	—	733
Warrant expense	—	—	(1,407)	(1,407)
Net loss	(37,158)	(27,610)	(36,360)	(121,342)
Common stock dividend to Series A Convertible Preferred stockholders	—	—	(5,861)	(5,861)
Net loss attributed to Common stockholders	$ (37,158)	$ (27,610)	$ (42,221)	$ (127,203)
Basic and diluted net loss per common share	$ (1.22)	$ (1.27)	$ (5.51)	
Weighted average common shares outstanding—basic and diluted	30,429,743	21,654,984	7,662,984	

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

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
(A development stage enterprise)
Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)
Period from June 28, 2006 (date of inception) through December 31, 2013
($ in thousands except for share amounts)

	Preferred Stock		Common stock		Additional paid-in capital	Deficit accumulated during development stage	Total stockholders' Equity/ (Deficit)
	Shares	Amount	Shares	Amount			
Balances at June 28, 2006 (Date of Inception)	—	$ —	—	$ —	$ —	$ —	$ —
Net loss	—	—	—	—	—	(123)	(123)
Balances at December 31, 2006	—	—	—	—	—	(123)	(123)
Issuance of Common stock to founders	—	—	2,125,096	2	—	—	2
Issuance of restricted Common stock to non-employees	—	—	2,180,000	2	—	—	2
Issuance of restricted Common stock to employees	—	—	457,170	1	—	—	1
Stock-based compensation expense	—	—	—	—	13	—	13
Net loss	—	—	—	—	—	(2,644)	(2,644)
Balances at December 31, 2007	—	—	4,762,266	5	13	(2,767)	(2,749)
Stock-based compensation expense	—	—	—	—	25	—	25
Contribution of services by stockholder	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	(3,799)	(3,799)
Balances at December 31, 2008	—	—	4,762,266	5	58	(6,566)	(6,503)
Issuance of Common stock to non-employees for services	—	—	5,000	—	—	—	—
Stock-based compensation expense	—	—	—	—	39	—	39
Contribution of services by stockholder	—	—	—	—	40	—	40
Net loss	—	—	—	—	—	(3,666)	(3,666)
Balances at December 31, 2009	—	—	4,767,266	5	137	(10,232)	(10,090)
Issuance of Convertible Preferred Stock Series A for cash	2,584,166	21,681	—	—	—	—	—
Issuance of Convertible Preferred Stock Series A upon conversion of debt and accrued interest	1,773,719	10,508	—	—	—	—	—
Costs related to issuance of Convertible Preferred Stock Series A, including Common stock warrants	—	(2,912)	—	—	621	—	621
Reclassification of fair value of warrant liability	—	—	—	—	234	—	234
Change in fair value of embedded conversion feature related to convertible debt	—	—	—	—	831	—	831
Issuance of Common stock to non-employees for services	—	—	23,836	—	82	—	82
Issuance of Common stock warrants to non-employees for services	—	—	—	—	38	—	38
Stock-based compensation expense	—	—	—	—	2,329	—	2,329
Contribution of services by stockholder	—	—	—	—	40	—	40
Net loss	—	—	—	—	—	(9,982)	(9,982)

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

CORONADO BIOSCIENCES, INC. AND SUBSIDIARIES
(A development stage enterprise)
Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)
Period from June 28, 2006 (date of inception) through December 31, 2013
($ in thousands except for share amounts)

	Preferred Stock		Common stock		Additional paid-in capital	Deficit accumulated during development stage	Total stockholders' Equity/ (Deficit)
	Shares	Amount	Shares	Amount			
Balances at December 31, 2010	4,357,885	29,277	4,791,102	5	4,312	(20,214)	(15,897)
Issuance of Convertible Preferred Stock Series B for purchase of Asphelia assets	2,525,677	16,114	—	—	—	—	—
Issuance of Convertible Preferred Stock Series C for cash	4,612,624	25,785	—	—	—	—	—
Costs related to issuance of Convertible Preferred Stock Series C, including the fair value of Preferred Stock Series C warrants	—	(4,171)	—	—	—	—	—
Issuance of Common stock for conversion of Convertible Preferred Stock Series A	(4,357,885)	(29,277)	4,357,885	4	29,273	—	29,277
Issuance of Common stock for conversion of Convertible Preferred Stock Series B	(2,525,677)	(16,114)	2,525,677	2	16,111	—	16,113
Issuance of Common stock for conversion of Convertible Preferred Stock Series C	(4,612,624)	(21,614)	4,612,624	5	21,609	—	21,614
Issuance of Common stock dividend to Preferred Stock Series A stockholders	—	—	2,178,917	2	(2)	—	—
Exercise of stock options	—	—	138,040	1	192	—	193
Warrant liability	—	—	—	—	2,693	—	2,693
Stock-based compensation expense	—	—	—	—	1,469	—	1,469
Contribution of services by stockholder	—	—	—	—	30	—	30
Net loss	—	—	—	—	—	(36,360)	(36,360)
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

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

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

	For the Year Ended December 31,			Period from June 28, 2006 (Date of Inception) to December 31,
	2013	2012	2011	2013
Cash flows from operating activities:				
Net loss	$ (37,158)	$ (27,610)	$ (36,360)	$ (121,342)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	5,902	3,638	1,469	13,414
Acquired in-process research and development	—	1,043	20,706	21,749
Noncash interest expense	536	130	—	2,434
Noncash interest expense—related parties	—	—	—	286
Contribution of services by stockholder	—	—	30	130
Issuance of Common stock to non-employee for services	—	—	—	121
Change in fair value of common stock warrant liability	—	—	—	234
Change in fair value of embedded conversion feature	—	—	—	831
Change in fair value of preferred stock warrant liability	—	—	1,407	1,407
Depreciation expense	17	3	22	61
Changes in operating assets and liabilities:				
Prepaid and other assets	(117)	(238)	(160)	(570)
Interest payable—related parties	—	(19)	19	—
Interest payable	(10)	119	—	109
Accounts payable and accrued expenses	1,184	(260)	1,915	4,398
Net cash used in operating activities	(29,646)	(23,194)	(10,952)	(76,738)
Cash flows from investing activities:				
Purchase of office equipment	(40)	(54)	—	(135)
Deposit for leasehold improvements	(148)	(225)	—	(373)
Purchase of in-process research and development	—	—	(3,843)	(3,843)
Net cash used in investing activities	(188)	(279)	(3,843)	(4,351)
Cash flows from financing activities:				
Proceeds from PCP notes payable—related party	—	—	—	570
Payment of PCP notes payable—related party	—	—	—	(570)
Payment of PCP notes payable—Asphelia asset purchase	—	(750)	—	(750)
Proceeds from notes payable—related parties	—	—	—	2,221
Proceeds from issuance of Series A Convertible Preferred Stock	—	—	—	21,681
Payment of costs related to the issuance of Series C Convertible Preferred Stock	—	—	—	(2,291)
Proceeds from issuance of Convertible Preferred Stock Series C	—	—	25,784	25,784
Payment of costs related to the issuance of Convertible Preferred Stock Series C	—	—	(2,884)	(2,884)
Proceeds from borrowings under line of credit	—	—	—	80
Payment of line of credit	—	—	—	(80)
Proceeds from Senior Convertible Notes	—	—	—	7,570
Payment of debt issue costs	—	—	—	(737)
Payment of notes payable—related parties	—	—	—	(600)
Proceeds from issuance of Common stock	92,399	28,855	193	121,452
Payment of costs related to the issuance of Common stock	(1,898)	(2,305)	—	(4,203)
Payment of principal of Hercules Note	(1,345)	—	—	(1,345)
Proceeds from issuance of Hercules Note	—	15,000	—	15,000
Payment of debt issue costs associated with Hercules Note	—	(288)	—	(288)
Net cash provided by financing activities	89,156	40,512	23,093	180,610
Increase in cash and cash equivalents	59,322	17,039	8,298	99,521
Cash—beginning of period	40,199	23,160	14,862	—
Cash—end of period	$ 99,521	$ 40,199	$ 23,160	$ 99,521

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

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

	For the Year Ended December 31,			Period from June 28, 2006 (Date of Inception) to December 31,
	2013	2012	2011	2013
Supplemental disclosure of cash flow information:				
Cash paid for interest	$ 1,387	$ 421	$ 53	$ 1,949
Supplemental disclosure of non-cash financing and investing activities:				
Issuance of Convertible Preferred Stock Series B for purchase of assets	$ —	$ —	$ 16,114	$ 16,114
Assumption of PCP Note related to Asphelia Asset Purchase	$ —	$ —	$ 750	$ 750
Issuance of Convertible Preferred Stock Series C warrants	$ —	$ —	$ 1,286	$ 1,286
Issuance of Common stock warrants related to the Convertible Preferred Stock Series A financing	$ —	$ —	$ —	$ 621
Conversion of Senior Convertible Notes into Convertible Preferred Stock Series A	$ —	$ —	$ —	$ 8,601
Conversion of notes payable—related parties into Convertible Preferred Stock Series A	$ —	$ —	$ —	$ 1,907
Issuance of Common stock for Convertible Preferred Stock Series A, B and C	$ —	$ —	$ 67,004	$ 67,004
Issuance of Warrant related to Hercules Note	$ —	$ 323	$ —	$ 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 (date of inception), is a biopharmaceutical company involved in the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer. As of December 31, 2013, the Company has two wholly owned subsidiaries Innmune Limited and TSO Development Corporation, Inc.

Development-Stage Risks and Liquidity

The Company is a development-stage enterprise. Activities to date include development of key compounds, establishing pre-commercial relationships, hiring qualified personnel and raising capital to fund operations. The Company continues to report as a development stage enterprise since planned principal operations have not yet commenced. Since inception, no revenue has been recognized.

On October 14, 2013 the Company reported that the TRUST-I study, its phase 2 randomized, double-blind, placebo-controlled, U.S. multi-centered study to evaluate the safety and efficacy of TSO in Crohn's Disease ("CD"), did not meet its primary endpoint of improving response, nor the key secondary endpoint of remission. In the overall patient population, response rate of patients on TSO did not separate from that of placebo.

In November 2013, Dr. Falk Pharma GmbH (Falk), its development partner informed the Company that an independent data monitoring committee (IDMC) had conducted a second interim analysis of data from approximately 240 patients who have 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, 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.

The Company has incurred recurring losses and experienced negative operating cash flows since inception and has an accumulated deficit of $121.3 million as of December 31, 2013. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales from its product candidates. To date, the Company's operations have been funded primarily by issuing equity and debt securities. During 2010, the Company issued 4,357,885 shares of Series A Convertible Preferred Stock ("Series A Shares") resulting in net proceeds to the Company of $19.4 million (see Note 11). All existing debt securities were either repaid or converted into Series A Shares as of December 31, 2010. During 2011, the Company completed an offering of 4,612,624 shares of Series C Convertible Preferred Stock ("Series C Shares") resulting in net proceeds to the Company of approximately $22.9 million (see Note 11). On November 15, 2011, the Company's Resale Registration Statement on Form S-1 was declared effective resulting in the conversion of 4,357,885 Series A Shares, 2,525,677 shares of Series B Convertible Preferred Stock ("Series B Shares") and 4,612,624 Series C Shares to Common stock. In June 2012, the Company completed a public offering of 5,750,000 shares of Common stock resulting in net proceeds of $26.4 million (See Note 11) and in August 2012, the Company received net proceeds of $14.7 million from a $15 million term loan with Hercules Technology Growth Capital (see Note 10). In October 2012, the Company entered into an At Market Issuance Sales Agreement (the "ATM") with MLV & Co. LLC ("MLV") pursuant to which the Company may issue and sell shares of Common stock having an aggregate offering price of up to $30.0 million. In 2012, the Company issued 3,361 shares of Common stock resulting in net proceeds of $19,000. During 2013, the Company issued 10,558,422 shares of Common stock pursuant to the Sales Agreement and received net proceeds of $89.4 million (see Note 11). In February 2014, the Company repaid the Hercules Loan Agreement in full and entered into a new Promissory Note with Israel Discount Bank of New York in the amount of $15.0 million (see Note 17).

The Company expects to incur substantial expenditures in the foreseeable future for the research, development and potential commercialization of its current and potentially new product candidates. The Company is continuing to evaluate the data from the TRUST-I trial and other current data on TSO and is awaiting the Clinical Study Report ("CSR") in connection with the TRUST-II trial to determine the future development plan for TSO. Until it has completed that process and made a determination regarding the future development for TSO, the Company does not expect its current level of expenditures to increase. However, the Company believes that cash on hand is sufficient to sustain operations for at least for the next 12 months. The Company would require additional financing to fully develop and obtain regulatory approvals for its product candidates, fund operating losses, establish manufacturing, and, if deemed appropriate, sales and marketing capabilities. The Company expects that it would need to seek funds through public or private equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to the Company on acceptable terms or at all. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, the Company will be required to delay, reduce or eliminate research and development programs, and pursue merger or acquisition strategies, if possible.

Operations of the Company are subject to other certain risks and uncertainties, including, but not limited to, uncertainty of product candidate development; technological uncertainty; dependence on collaborative partners; uncertainty regarding patents and proprietary rights; regulatory approvals and other comprehensive government regulations; having no commercial manufacturing, marketing or sales capability or experience; and dependence on key personnel. Any significant delays in the development or marketing of products could have a material adverse effect on the Company's business and financial results.

The Company sources certain critical components from single source suppliers. If the Company is required to purchase these components from an alternative source, it could adversely affect development of the Company's product candidates.

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 its 100% owned subsidiaries, Innmune Limited and TSO Development Corporation, Inc. 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, the valuation of its common stock ("Common stock") prior to the Company becoming public and Common stock warrants, stock options, accrued expenses, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from our estimates.

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 GmbH ("Ovamed") to supply it with its requirements of *Trichuris suis* ova ("TSO"). Ovamed is the sole supplier of this product, which it is currently producing at only one facility in Germany, where it is also producing product for third parties, including Dr. Falk Pharma GmbH ("Falk"). Ovamed also relies on certain other suppliers for materials and services. Similarly, the Company currently relies on BioReliance Corporation, Progenitor Cell Therapy LLC 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 Concentration of Credit Risk

The Company currently maintains all cash in one institution in the United States. Balances at this institution may exceed Federal Deposit Insurance Corporation insured limits.

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 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, 2013 and 2012 the Company recorded deferred financing costs of $43,000 and $63,000, respectively, in other assets in the accompanying consolidated balance sheets.

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. The Company is currently evaluating its plans for its manufacturing facility in Woburn, MA for which related long-lived assets are $373,000. To date, the Company has not recorded any impairment losses on long-lived assets.

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 Issued Accounting Standards

In December 2011, the FASB issued Accounting Standard Update No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*. The amendments in this update require an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. An entity is required to apply the amendments for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. An entity should provide the disclosures required by those amendments retrospectively for all comparative periods presented. This guidance became effective for the Company in 2013. Adoption of this standard did not have a material impact on the Company's financial position, statement of operations, or statement of cash flows.

3. 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 attributable to common stockholders 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 attributable to common stockholders by the weighted-average number of Common stock and Common stock equivalents outstanding for the period. For purposes of this calculation, Common stock equivalents are not included in the calculation of diluted net loss per share.

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

	For the year ended December 31,		
	2013	2012	2011
($ in thousands except share and per share amounts)			
Historical net loss per share:			
Numerator			
Net loss	$ (37,158)	$ (27,610)	$ (36,360)
Common stock dividend to Series A Preferred stockholders	—	—	(5,861)
Net loss attributed to Common stockholders	$ (37,158)	$ (27,610)	$ (42,221)
Denominator			
Weighted-average common shares outstanding—Denominator for basic and diluted net loss per share	30,429,743	21,654,984	7,662,984
Basic and diluted net loss per share attributed to common stockholders	$ (1.22)	$ (1.27)	$ (5.51)

The Company's potential dilutive securities which include convertible preferred stock, unvested restricted stock, 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,		
	2013	2012	2011
Series A Shares	—	—	3,796,733
Series B Shares	—	—	2,158,935
Series C Shares	—	—	1,966,635
Unvested restricted Common stock	—	—	—
Warrants to purchase Common stock	1,012,977	1,091,558	804,949
Options to purchase Common stock	3,936,199	2,279,603	1,479,291
Restricted Stock	140,995	—	—
	5,090,171	3,371,161	10,206,543

4. Property and Equipment

Property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	As of December 31, 2013	2012
Construction in progress	N/A	$ 373	$ —
Computer equipment	3	13	10
Furniture & fixtures	5	69	38
Leasehold improvements	5	12	6
Total property and equipment		467	54
Less: Accumulated depreciation		(20)	(3)
Property and equipment, net		$ 447	$ 51

Construction in progress relates to payments made in connection with the build-out of our Woburn, MA manufacturing facility.

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.

5. Accrued Liabilities and other Long-Term Liabilities

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

	As of December 31, 2013	2012
($ in thousands)		
Accrued expenses:		
Salaries, bonuses and related benefits	$ 450	$ 1,064
Severance (Note 15)	1,502	354
Professional fees	351	320
Research and development expenses	1,245	403
State franchise taxes	190	—
Ovamed manufacturing rights – short-term component (Note 14)	500	—
Other	192	44
Total accrued expenses	$ 4,430	$ 2,185
Other long-term liabilities:		
Hercules Note end of term charge (Note 10)	398	398
Ovamed manufacturing rights – long-term component (Note 14)	679	1,043
Total other long-term liabilities	$ 1,077	$ 1,441

6. Commitments and Contingencies

Operating Lease Obligations

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. Total rent expense for the term of this lease will be approximately $366,000. The Company commenced occupancy of this space in May 2013.

Pursuant to the Second Amendment and Agreement, ("the Manufacturing Agreement") (see Note 14), in December 2012, the Company entered into an Assignment and Assumption of Lease ("Assignment") with TSO Laboratories, Inc., a wholly-owned subsidiary of Ovamed GmbH, ("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 will approximate $590,000 at an average annual rate of $118,000. As of December 31, 2013, the Company spent $373,000 in leasehold improvement costs associated with this lease.

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. Total rent expense for the term of this lease will approximate $470,000. The Company took occupancy of this space in October 2012.

In July 2011, the Company entered into a twelve-month lease for office space under an operating lease which expired on October 31, 2012. In October 2010, the Company entered into a three-month renewable agreement for office facilities under an operating lease. This operating lease terminated in September 2012.

Total future minimum lease payments under these leases are:

($ in thousands)	
2014	$ 351
2015	365
2016	291
2017	202
2018	22
Total minimum lease payments	$ 1,231

The Company recognizes rent expense on a straight-line basis over the non-cancellable lease term. Rent expense for the years ended December 31, 2013, 2012 and 2011 and the period from inception to December 31, 2013 was $284,000, $93,000, $165,000, and $641,000, 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 subsidiary 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 subsidiary.

7. Employee Benefit Plans

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, 2013 and 2012, the Company paid a matching contribution of $107,000 and $85,000, respectively. No match was paid in prior years.

8. Fair Value Measurement

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured 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. 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 accrued Ovamed Manufacturing 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, is $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.

9. Related Party Transactions

Placement Agent

Paramount BioCapital, Inc. ("PBC"), is an affiliate of our Chairman, President and Chief Executive Officer and one of our principal stockholders. PBC acted as placement agent for the private placement of the Company's Senior Convertible Notes, PCP Notes, and Series A Shares (see Note 10). For the services rendered, PBC received cash payments for commissions and reimbursement of expenses as well as warrants to purchase common stock (see Notes 10 and 12).

Other Related Parties

Our Chairman, President and Chief Executive Officer, individually and through certain trusts over which he has voting and dispositive control, beneficially owned approximately 14.1% of the Company's issued and outstanding common stock as of December 31, 2013 and 2012. Our Executive Vice Chairman, Strategic Development individually owns approximately 15.0% of the Company at February 20, 2014.

National Securities Corporation, or National, the placement agent for our Series C Share financing, is a related party to the Principal Stockholder/Director, President and Chief Executive Officer of the Company. National acted as an underwriter of our June 2012 public offering of common stock and received related commissions of $187,000 in connection with the offering.

10. Debt

Hercules Debt Agreement

In August 2012, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Technology Growth Capital, Inc. ("Hercules") pursuant to which the Company issued a $15 million note and received net proceeds of $14.7 million. The loan bears 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 matures on March 1, 2016. The loan requires interest-only payments for the initial 12 months and thereafter requires repayment of the principal balance with interest in 30 monthly installments. The Company may 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 is 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 has 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 our 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, 2013 and 2012, interest expense related to the Hercules loan was $1,767,000 and $609,000, respectively, including $381,000 and $123,000 related to accretion of the debt discount, respectively. At December 31, 2013, the current portion of the Hercules Note of $6,203,000 and noncurrent portion of $7,017,000 which is net of the debt discount of $434,000 was recorded on the Consolidated Balance Sheet. Principal payments for the note are scheduled to be $6,203,000 in 2014, $6,866,000 in 2015 and $587,000 in 2016, respectively.

Related Party Notes

The Company issued a series of 8% promissory notes to related parties for expenses paid on behalf of the Company as well as advances made directly to the Company (collectively, the "Related Party Notes"). On June 28, 2006, the Company issued a four-year promissory note payable to PBS (the "PBS Note"). PBS is a related party given common ownership with the Company's Chairman, President and Chief Executive Officer and one of its principal stockholders. On July 30, 2007 and January 17, 2008, the Company issued three-year promissory notes which were payable to trusts established for the benefit of the family of the sole member of PBS and the Company's Chairman, President and Chief Executive Officer and one of its principal stockholders.

The Related Party Notes mature and were payable on or upon the occurrence of certain events defined in the agreement on September 4, 2008, the Company amended the Related Party Notes to provide that all unpaid principal and accrued interest shall be automatically converted into the Company's common stock upon the initial closing of a private placement of the Company's common stock at a conversion price equal to 100% of the lowest price paid by investors of the offering. On July 7, 2009, the Company amended the Related Party Notes to change the maturity date to February 20, 2010 and to provide that all unpaid principal and accrued interest shall be automatically converted upon the occurrence of certain events including a qualified financing, a reverse merger or a sale of the Company, as defined.

On February 5, 2010, the Company amended the Related Party Notes to extend the maturity date to September 30, 2010 and these amendments were accounted for as a modification and the change in the fair value of the conversion feature, in the amount of $0.1 million, was recorded as a debt discount. The debt discount was amortized to interest expense in the consolidated statement of operations over the remaining term of the Related Party Notes.

In 2010, the Company completed a qualified financing defined as an equity financing or series of related financings greater than $10 million at a conversion price equal to 75% of the lowest price per unit paid for such securities in cash by investors. This qualified equity financing resulted in the Related Party Notes, principal and accrued interest totaling $1.6 million to automatically convert into 273,046 shares of Series A Shares at a per share price of $5.87. In addition, under the PBS Note, all principal borrowed and interest accrued subsequent to January 20, 2010 totaling $0.3 million was converted into 36,194 Series A Shares at a per share price of $8.39.

PCP Promissory Notes (the "PCP Notes")

In 2009, the Company issued 10% promissory notes to Paramount Capital Partners ("PCP") for aggregate gross proceeds of $570,000. PCP is a related party due to common ownership with the Company's Chairman, President and Chief Executive Officer and one of its principal stockholders. All unpaid principal and accrued interest outstanding under the PCP Notes were payable on December 31, 2013 or earlier in the event of certain conditions. The outstanding principal and accrued interest totaling $0.6 million was repaid in cash in 2010.

In conjunction with entering into the PCP Notes, the Company issued warrants to purchase 27,175 shares of common stock (see Note 12). These warrants were increased to 40,787 shares pursuant to an anti-dilution provision. A portion of the proceeds was allocated to the fair value of the warrants and recorded as a debt discount and was amortized to interest expense in the consolidated statement of operations over the term of the PCP Notes. PCP received cash commissions equal to 2% of the gross proceeds of the PCP Notes and expense reimbursements as compensation for its services as the placement agent. These costs were capitalized as deferred financing fees and are amortized to interest expense in the consolidated statement of operations over the term of the PCP Notes.

On January 7, 2011, as part of the Asphelia Asset Purchase (see Note 14), the Company assumed a $750,000 10% promissory note issued to PCP by Asphelia. All unpaid principal and accrued interest outstanding under this note was payable on the earlier of (i) December 31, 2013, or (ii) the consummation certain corporate transactions. The PCP Note was classified as a long-term liability at December 31, 2011 and was paid in full in 2012.

Senior Convertible Notes

In 2008, the Company issued 8% convertible promissory notes for cash proceeds of $4.1 million (the "2008 Senior Convertible Notes") that were secured by a first priority security interest in all of the Company's assets. The 2008 Senior Convertible Notes were due on February 20, 2009. The 2008 Senior Convertible Notes included an option to extend maturity for one year until February 20, 2010 during which time the interest rate would increase to 10%. In February 2009, the Company exercised its option to extend the term of the 2008 Senior Convertible Notes. As a result of the term extension and increased interest rate provision related to the 2008 Senior Convertible Notes, the Company recorded interest expense using the effective interest method based on the estimated life of two years.

In 2009 the Company issued 8% convertible promissory notes for cash proceeds of $3.5 million (the "2009 Senior Convertible Notes") that were secured by a first priority security interest in all of the Company's assets. The 2009 Senior Convertible Notes were due on February 20, 2010.

The 2008 Senior Convertible Notes and the 2009 Senior Convertible Notes (collectively, "Senior Convertible Notes") provided that all unpaid principal and accrued interest were convertible into the Company's equity securities upon the occurrence of certain events including a qualified financing, a reverse merger or a sale, as defined.

In 2010, the Company amended the Senior Convertible Notes to extend the maturity date to September 30, 2010 and modify the conversion price factor for certain events. The amendment was accounted for as a modification and the change in the fair value of the conversion feature, in the amount of $0.7 million, was recorded as a debt discount. The debt discount was amortized to interest expense in the consolidated statement of operations over the remaining term of the Senior Convertible Notes.

The Company also provided the Senior Convertible Noteholders a repayment premium of 42.9% of the aggregate principal plus accrued interest in the event the Senior Convertible Notes did not automatically convert prior to September 30, 2010. This premium was bifurcated from the debt and is reflected as a separate liability. The initial fair value and subsequent changes in fair value were recognized as interest expense in the consolidated statement of operations.

In 2010, the Company completed a qualifying financing and Senior Convertible Notes principal and accrued interest totaling $8.6 million automatically converted into 1,464,479 Series A Shares with a per share price of $5.87. In addition, the liability of $0.6 million related to the repayment premium was reflected as interest expense upon the conversion of the Senior Convertible Notes to Series A Shares.

PBC was entitled to receive commissions equal to 7% of the gross proceeds of the Senior Convertible Notes, expense reimbursements, and warrants to purchase common stock (as defined in Note 13) as compensation for its services as the placement agent for the Senior Convertible Notes. These issuance costs of $0.8 million were capitalized as deferred financing costs and were amortized to interest expense in the consolidated statements of operations over the estimated life of the Senior Convertible Notes.

Interest expense for all debt is as follows:

	For the Year Ended December 31,			Period from June 28, 2006 (Date of Inception) to
($ in thousands)	2013	2012	2011	December 31, 2013
Interest expense	$ 1,903	$ 609	$ —	$ 3,544
Interest expense—related parties	—	55	74	503
Amortization of embedded conversion feature	—	—	—	831
Change in fair value of common stock warrant liability	—	—	—	234
Amortization of deferred financing fees	20	6	—	764
Total interest expense	$ 1,923	$ 670	$ 74	$ 5,876

11. Equity

Convertible Preferred Stock

Series A Shares

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 15,000,000 shares of $0.001 par value Preferred Stock. As of December 31, 2013 and 2012, there were no Series A Shares outstanding. See "Conversion of Series A, B and C Shares" below.

Conversion of Series A, B and C Shares

On November 15, 2011, the Company's Form S-1 was declared effective resulting in the conversion of 4,357,885 Series A Shares, 2,525,677 Series B Shares and 4,612,624 Series C Shares into 11,496,186 shares of common stock. Accordingly, at December 31, 2013 and 2012, the Company had no outstanding Preferred Stock.

Common Stock

On September 30, 2013, the Company's Stockholders' approved an amended and restated certificate of incorporation, to increase the number of authorized shares of capital stock from 65,000,000 shares to 115,000,000 shares and to increase the number of authorized shares of $0.001 par value Common Stock from 50,000,000 to 100,000,000.

The terms, rights, preference and privileges of the Company's common stock are as follows:

Voting Rights

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. 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.

On June 1, 2007, the Company issued the following shares of common stock:

- 2,125,096 shares of fully vested common stock to its founders at par value of $0.001.
- 457,170 shares of restricted common stock were granted to certain employees of the Company under the Company's 2007 Stock Incentive Plan, for payment of par value (see Note 13). The shares vest annually in equal amounts over three years and the fair value of the awards was determined and fixed on the grant date. Compensation expense is recorded on a straight-line basis over the vesting period.
- 2,180,000 shares of restricted common stock were issued to certain employees of PBS at par value of $0.001 that vest annually in equal amounts over three years (see Note 13). PBS provided various services to the Company. The fair value of the awards was determined on the grant date and the unvested awards were remeasured each reporting period. Compensation expense is recorded on a straight-line basis over the vesting period.

In 2009, the Company issued 5,000 shares of fully vested common stock for compensation of past services performed by a non-employee. The fair value of the shares, which was not material, was recorded as research and development expense in the consolidated statements of operations on the grant date.

In 2010, the Company issued 23,836 shares of fully vested common stock for compensation of past services performed by a non-employee. The fair value of the shares of $82,000 on the grant date was recorded as research and development expense in the consolidated statements of operations on the grant date.

In 2011, pursuant to the exercise of options, the Company issued 138,080 shares of common stock with proceeds of $193,000, which were recorded in additional paid in capital.

In May 2011, the Special Dividend was declared resulting in the issuance of 2,178,917 shares of common stock.

In November 2011, upon the effectiveness of the Company's Form S-1, an aggregate of 11,496,186 shares of Preferred Stock converted into common stock (see Convertible Preferred Stock above).

In June 2012, the Company completed an underwritten public offering of 5,750,000 shares of our common stock, including 750,000 shares subject to an over-allotment option exercised by the underwriters, at a price of $5.00 per share for proceeds, net of underwriting commissions and other offering expenses, of approximately $26.4 million.

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 ATM's 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.

12. Warrants to Purchase Common Stock

Debt Placement Agent Warrants

In connection with the issuance of the Senior Convertible Notes (see Note 10), the Company issued seven-year warrants to purchase the Company's common stock to PBC as partial consideration for its services as the placement agent. The number of warrants and the exercise price were dependent upon i) the lowest price paid in a qualified financing, ii) consideration received in a sale of the company, or iii) consideration received in a reverse merger. If none of these events occurred before the second anniversary of the issuance date, the Debt Placement Warrants would be exercisable for a number of shares of common stock equal to 10% of the principal amount of the Senior Convertible Notes divided by $1.00, at a per share exercise price of $1.00.

In connection with the Series A Shares offering on April 26, 2010, a qualified financing, both the number of warrants and the exercise price became known. The placement agent received warrants for shares of the Company's common stock equal to 10% of the principal amount of the Senior Convertible Notes divided by the lowest price paid for securities in the Series A Shares offering, at an exercise price of 110% of the lowest price paid for securities in a qualified financing. Pursuant to the Series A Shares offering, PBC was issued warrants for an aggregate of 48,510 shares of common stock at an exercise price of $9.23 per share with a fair value of $0.1 million related to the 2008 Senior Convertible Notes and warrants for an aggregate of 41,716 shares of common stock at an exercise price of $9.23 per share with a fair value of $0.1 million related to the 2009 Senior Convertible Notes. In April 2010, the total fair value $0.2 million of the warrants was reclassified from a liability to additional paid-in capital.

PCP Warrants

In connection with the issuance of the PCP Notes in 2009 (see Note 10), the Company also issued to PCP warrants to purchase shares of the Company's common stock. The number of warrants and the exercise five-year price were dependent upon i) the lowest price paid in a qualified financing or ii) consideration received in a reverse merger. If none of these events occurred before the second anniversary of the issuance date, the number of warrants would equal 40% of the principal amount of the PCP Notes divided by $1.00, at a per share exercise price of $1.00.

The fair value of the warrants was measured on the date of issuance using a Black-Scholes option pricing model and was not material to the consolidated financial statements.

In connection with the Series A Shares offering, a qualified financing, both the number of PCP warrants and the exercise price became known. The placement agent received warrants for the number of shares of the Company's common stock equal to 40% of the principal amount of the PCP Notes divided by the lowest price paid for securities in the Series A Shares offering, at an exercise price of 110% of the lowest price paid for securities in the offering. The Company issued warrants to purchase an aggregate of 27,175 shares of common stock at an exercise price of $9.23 per share for a fair value of $47,000 which was reclassified as additional paid-in capital. In 2011, due to a lowest price paid provision, the original warrants converted to warrants for 40,787 shares exercisable at $6.15.

Preferred Stock Placement Warrants

In connection with the issuance of the Company's Series A Shares, the Company issued seven-year warrants to purchase an aggregate of 258,421 shares of the Company's common stock at an exercise price of $8.39 per share to PBC as partial consideration for its services as the placement agent.

The fair value of the warrants was $0.6 million measured on the respective date of issuance and were recorded as a reduction in the carrying value of the Preferred Stock and an increase to additional paid in capital. The fair values were determined using an option pricing model assuming 92.0% — 94.4% volatility, a 2.0% — 3.3% risk-free rate of interest, a term of seven years and an estimated fair value of the Company's common stock of $3.45 per share. The warrants were accounted for as stock issuance costs; and the fair value was recorded as a reduction to the carrying amount of the Series A Shares with a corresponding increase to additional paid-in capital.

Non-Employee Warrants

On November 22, 2010, the Company issued five-year warrants to purchase 41,716 shares of the Company's common stock at an exercise price of $9.23 per share to a non-employee for consulting services. The fair value of the warrants on the date of issuance was $38,000 and was determined using an option pricing model assuming 93.7% volatility, a 1.4% risk-free rate of interest, a contractual life of five years and an estimated fair value of the Company's common stock of $1.96 per share. The fair value of the warrants was recorded as research and development expense, with a corresponding increase to additional paid in capital, in the consolidated statements of operations on the grant date as the warrant was fully vested and no future service was required.

In February 2011, the Company issued fully-vested five-year warrants to purchase 50,000 shares of the Company's common stock at an exercise price of $1.37 per share to a non-employee for consulting services. The initial fair value of the warrants was calculated using a Black-Scholes option-pricing model with the following assumptions: five-year contractual term; 93.2% volatility; 0% dividend rate; and a risk-free rate of 2.65%. The fair value of the warrants was determined to be $69,000 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of research and development expense in the consolidated statements of operations.

In March 2011, the Company issued 10-year warrants to purchase 60,000 shares of the Company's common stock at an exercise price of $1.37 per share for consulting services provided by a non-employee. The warrants vest over six months. The initial fair value of the warrants was calculated using a Black-Scholes option-pricing model with the following assumptions: ten-year contractual term; 95.4% volatility; 0% dividend rate; and a risk-free rate of 3.58%. The fair value of the warrants was determined to be $98,000 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of research and development expense in the consolidated statements of operations. This warrant was marked to market at each reporting date until it was fully vested in September 2011.

In September 2011, the Company issued warrants to purchase 75,000 shares of the Company's common stock at an exercise price of $2.95 per share as compensation for services provided by consultants. The warrants expire on the third or fifth anniversaries of their issuance dates and vest at various times over two years. The initial fair value of the warrants was calculated using a Black-Scholes option-pricing model with the following assumptions: three to five years; 90.8% — 96.3% volatility; 0% dividend rate; and a risk-free rate of 0.4% to 0.9%. The initial fair value of the warrants was determined to be $144,000 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of research and development expense in the consolidated statements of operations. The fair value of these awards was marked-to-market on each valuation date using the Black Scholes pricing model until such time that these awards were fully vested.

In December 2011, the Company issued warrants to purchase 5,000 shares of the Company's common stock at an exercise price of $6.00 per share for consulting services provided by a non-employee. The warrants expire on the third anniversary of its issuance date and vest over two years. The initial fair value of the warrants was calculated using a Black-Scholes option-pricing model with the following assumptions: three-year term; 91.1% volatility; 0% dividend rate; and a risk-free rate of 0.4%. The initial fair value of the warrants was determined to be approximately $19,100 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of research and development expense in the consolidated statements of operations. The fair value of this award was marked-to-market on each valuation date using the Black Scholes pricing model until such time that the award was fully vested.

On April 2, 2012, pursuant to a cashless exercise of 25,000 warrants the Company issued 20,970 shares of common. The warrants were granted at $1.37 per share and the fair value on the date of exercise was $8.50.

On August 16, 2012, the Company issued a fully vested warrant to purchase 25,000 shares of common stock at a purchase price of $5.72 as compensation for consulting services provided by a non-employee. The warrant expires on the fifth anniversary of its issuance date. The fair value of the warrant was calculated using a Black-Scholes option-pricing model with the following assumptions: five-year contractual term; 110.3% volatility; 0% dividend rate; and a risk-free interest rate of 0.83%. The fair value of the warrants was determined to be $113,000 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of general and administrative expense in the consolidated statements of operations. On August 16, 2012, the Company issued a fully vested warrant to purchase 20,000 shares of common stock at an exercise price of $5.72 as compensation for consulting services provided by a non-employee. The warrant expires on the sixth anniversary of its issuance date. The fair value of the warrants was calculated using a Black-Scholes option-pricing model with the following assumptions: six-year contractual term; 104.51% volatility; 0% dividend rate; and a risk-free interest rate of 1.06%. The fair value of the warrant was determined to be $92,000 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of general and administrative expense in the consolidated statements of operations.

On August 28, 2012, the Company issued a fully vested warrant to purchase 73,009 shares of common stock at an exercise price of $5.65 per share to Hercules in connection with the Loan Agreement. (See Note 10.)

On December 18, 2012 the Company issued two fully vested warrants to purchase 35,000 shares of common stock at an exercise price of $4.88 as compensation for consulting services provided by two non-employees. The warrant expires on the third anniversary of its issuance date. The fair value of the warrants was calculated using a Black-Scholes option-pricing model with the following assumptions: three-year contractual term; 97.45% volatility; 0% dividend rate; and a risk-free interest rate of 0.28%. The fair value of the warrants was determined to be $103,000 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of general and administrative expense in the consolidated statements of operations.

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.

Warrants to Purchase Series C Shares

In connection with the Company's Series C Share offering, the Company (i) paid to NSC, a related party, as consideration for its services as the placement agent, a fee equal to 10% of the gross proceeds of the issuance, or $2.6 million, and (ii) issued five-year warrants to NSC to purchase an aggregate of 461,263 Series C Shares at an exercise price of $5.59 per share. The fair value of these warrants was $1.3 million as measured on the date of issuance and was recorded as a reduction in the carrying value of the Series C Shares and a warrant liability. The warrants were marked-to-market each reporting period until November 15, 2011.

Upon the effectiveness of the Company's Form S-1 on November 15, 2011, these warrants became exercisable for common stock and a final marked-to-market valuation was performed resulting in a charge of $1.4 million as of this date. The final fair value of $2.7 million was then reclassed to additional paid in capital. The fair value was determined using an option pricing model assuming a 92.4% volatility, 0.93% risk-free rate of interest, a term of five years and a fair value of the Company's common stock of $8.00 per share, based upon the price of the first trade of the Company's stock in the public market.

On April 2, 2012 pursuant to the cashless exercise provision the Company issued 534 shares of common stock in exchange for the exercise of 2,986 shares of common stock. The fair market value of common stock on the date of exercise was $6.81 and the exercise price of the warrants was $5.59.

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.

At December 31, 2013, the Company had outstanding warrants of 711,895.

13. 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 are determined by the board of directors.

The purpose of the Plans are to provide the Company with the flexibility to use shares, options or other awards based on the Company's common stock as part of an overall compensation package to provide 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 are 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 7,303,280 were granted, net of cancellations, and 996,720 shares were available for issuance as of December 31, 2013.

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 very 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 stratification of option-holder groups. Employee options meet the criteria for the Simplified Method under SAB 107, while, while 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 year ended December 31, 2013 was $3.77. The following assumptions were used:

Stock option plans	2013	2012
Exercise price	$1.71–$9.21	$4.75–$7.84
Expected stock price volatility	81.3%–112.7%	87.3%–114.3%
Risk free rate of interest	1.01%–3.04%	0.16%–2.23%
Expected life of options	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, 2013, 2012 and 2011, and from the period June 28, 2006 (Date of Inception) December 31, 2013:

($ in thousands)	2013	2012	2011	Period from June 28, 2006 (Date of Inception) to December 31, 2013
Employee awards	$ 4,867	$ 2,408	$ 520	$ 8,072
Non-employee awards	897	664	662	4,310
Non-employee warrants	138	566	287	1,032
Total compensation expense	$ 5,902	$ 3,638	$ 1,469	$ 13,414

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, 2012	2,519,070	$ 3.37	$ 2,860	8.54
Options granted	2,466,590	$ 5.34	—	
Options exercised	(550,157)	$ 1.76	478	
Options cancelled/forfeited	(1,317,726)	$ 5.51	—	
Outstanding at December 31, 2013	3,117,777	$ 4.31	$ —	8.36
Options vested and expected to vest	3,117,777	$ 4.31	$ —	8.36
Options vested and exercisable	2,169,444	$ 3.75	$ —	7.87

As of December 31, 2013, the Company had unrecognized stock-based compensation expense related to all unvested stock options of $3.4 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.3 years.

During the year ended December 31, 2013, exercises of stock options resulted in total proceeds of approximately $1.0 million.

Restricted Stock

During 2013, the Company granted restricted shares of our common stock to an executive and a director of the Company. Such restricted stock awards shall vest based upon both the passage of time as well as certain pre-defined market conditions. The fair value of the restricted stock awards of $7.6 million was estimated on the grant date using the Monte Carlo simulation model and expensed using a graded vesting methodology. 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.

Stock-based compensation expense from restricted stock awards for the year ended December 31, 2013 and the period from inception to December 31, 2013 was $66,000 and $2.2 million, respectively. There was no stock-based compensation expense related to restricted stock awards for the years ended December 31, 2012 and December 31, 2011.

The following table summarizes restricted stock activity:

	Restricted Stock	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2012	—	$ —
Restricted stock granted	3,958,692	1.93
Restricted stock vested	—	—
Restricted stock forfeited	—	—
Unvested balance at December 31, 2013	3,958,692	$ 1.93

As of December 31, 2013, the Company had unrecognized stock-based compensation expense related to all unvested restricted stock awards of $7.6 million, which is expected to be recognized over the remaining weighted-average vesting period of 5.0 years.

Employee Stock Purchase Plan

On December 19, 2011, the board of directors approved the 2012 Coronado Employee Stock Purchase Plan 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, 2013, 49,214 have been purchased and 150,786 are available for future sale under the ESPP. The Company recognized share-based compensation expense of $46,000 and $95,000 for the years ended December 31, 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. Common 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 Company's ESPP. Common 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 Company's ESPP. Common 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.

14. License Agreements

TSO

Asphelia Asset Purchase

On January 7, 2011, the Company entered into an asset purchase agreement (the "Asphelia Asset Purchase" or the "Asphelia Agreement") with Asphelia Pharmaceuticals, Inc. ("Asphelia"). Pursuant to the terms of the Asphelia Agreement, the Company paid $20.7 million, including assumption of certain Asphelia liabilities, for the purchase of Asphelia's assets relating to TSO, an early-stage developmental compound.

In exchange, the Company issued 2,525,677 Series B Shares with a fair value of $6.38 per share, assumed the PCP Note in the principal amount of $750,000 and paid cash of approximately $3.8 million, including a $3.4 million payment to Ovamed, and $0.4 million for repayment of Asphelia's debt, $61,000 of which was paid to a related party. The total consideration paid in connection with the Asphelia Asset Purchase is as follows:

($ in thousands)		
Fair value of 2,525,677 Series B Shares	$	16,114
Cash payment		3,809
Fair value of PCP Note		750
Other transaction costs		33
Total asset acquisition cost	$	20,706

The transaction was treated as an asset acquisition as it was determined that the assets acquired did not meet the definition of a business. In accordance with accounting guidance, 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. The assets purchased from Asphelia require substantial completion of research and development, regulatory and marketing approval efforts in order to reach technological feasibility. Accordingly, the purchase price of $20.7 million was reflected as acquired in-process research and development in the consolidated statement of operations for year ended December 31, 2011.

In connection with the Asphelia Asset Purchase, Asphelia assigned the Exclusive Sublicense Agreement, dated December 2005, between Asphelia and Ovamed (as amended, the "Ovamed License") and Manufacturing and Supply Agreement dated March 2006, between Asphelia and Ovamed (as amended, the "Ovamed Supply Agreement") to the Company and the Company assumed Asphelia's obligations under these agreements. Under the Ovamed License, the Company has exclusive rights (which were licensed by Ovamed from the University of Iowa Research Foundation), including sublicense rights, in North America, South America and Japan, and know-how to make, use and sell products covered by these patents and know-how.

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 acquired pursuant to the Asphelia Asset Purchase, 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 ("FU 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 is expected to be four years, during which the Company will pay FU Berlin a total maximum amount of approximately €648,000, or approximately $853,000 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 the Company terminates the Research Agreement, the Company must pay FU Berlin a termination fee comprised 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. For the year ended December 31, 2013, the Company incurred sponsored research expense of $183,200, which was reflected in research and development expense.

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 $4,982,000 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. 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 $1,333,000, 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. Pursuant to the Manufacturing Agreement, Ovamed granted the Company with an exclusive license to make TSO for the Coronado Territory, terminating Ovamed's exclusive supply rights in Coronado Territories 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 2014 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 U.S. Food and Drug Administration "FDA" approval of a Biologics License Application 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 Territory exceed an agreed amount.

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 in which we initially planned to establish a TSO manufacturing facility. The Company is currently evaluating its TSO manufacturing plans and will continue to purchase supply from Ovamed. 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.

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 $6.5 million) 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 $1.4 million) 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 $2.0 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 $3.4 million) in the first half of 2014 upon receipt of the CSR.

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 UCL Business PCL ("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.

BcL—2

In November 2006, the Company entered into a license agreement with the Burnham Institute for Medical Research ("Burnham") and amended this license agreement in November 2007 for the exclusive, worldwide rights to several BcL-2 inhibitor compounds, including BcL-2, for the treatment of cancer and other diseases driven by increases in BcL-2 pro-survival proteins. In 2010, in consideration for the initial license, the Company paid the Burnham an up-front fee of $50,000 and, in connection with the amendment of the license agreement to add additional compounds discovered under the terms of our sponsored research arrangement with the Burnham, the Company made an additional payment of $25,000 to the Burnham. In February 2011, the Company provided Burnham with written notice which terminated the licenses on May 10, 2011.

15. Executive Officer Agreements

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 will pay him $900,000 in severance. 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.

Lindsay A. Rosenwald

On December 19, 2013, the Company's board of directors appointed current director Dr. Lindsay A. Rosenwald, as the Company's new 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 will pay Dr. Rosenwald an annual base salary of $28,275. Dr. Rosenwald will also be eligible for a discretionary bonus based on his achievement of performance goals and objectives as established by our 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. Such shares shall vest based upon both predefined market conditions and continued employment with or service on the Company's Board.

Michael S. Weiss

On December 19, 2013, the Company appointed Mr. Michael S. Weiss to the board of directors to serve as the Co-Vice Chairman. In connection with this appointment the Company issued Mr. Weiss 1,979,346 shares of restricted stock for services to be rendered. In February 2014, Mr. Weiss was appointed Executive Vice Chairman, Strategic Development (see Note 17).

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 $143,000 of the severance obligation as of December 31, 2013. 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, the Chief Medical Officer. Pursuant to the employment agreement, the Company will pay Dr. Horgan an annual base salary of $340,000. At the discretion of our board of directors, he also will be 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 our 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 our company (see Note 17).

Glenn L. Cooper

On December 28, 2012, the Company's Executive Chairman, Dr. Glenn L. Cooper, resigned from his position as Executive Chairman and as a director of the Company, effective immediately and the Company entered into a separation and release agreement and a one-year consulting agreement with Dr. Cooper, pursuant to which Dr. Cooper was paid $25,000 per month for 12 months as well as his COBRA premiums for 12 months. The Company also paid him $30,000 in severance. Dr. Cooper's current options outstanding at the time of separation continued to vest during the term of his consulting agreement and became fully vested as of December 31, 2013. On December 28, 2012, the Company also granted Dr. Cooper an option to purchase 25,000 shares of common stock at an exercise price of $4.75 per share. The options vested on December 28, 2013. Upon the execution of the separation and release and consulting agreements, the employment agreement between the Company and Dr. Cooper dated April 1, 2011 was terminated.

The Company assessed under Accounting Standards Codification 718 Compensation – Stock Compensation, the substance of Dr. Cooper's consulting agreement and concluded that the agreement would be accounted for as a severance arrangement as the agreement does not provide any specific deliverables, projects or contain a minimum work requirement. As a result, all related compensation cost was recognized immediately on December 28, 2012. During 2012, the modification of Dr. Cooper's existing stock options to allow for continued vesting through December 31, 2013 resulted in incremental cost and charge to operations of approximately $470,000 and the grant-date fair value of Dr. Cooper's option to purchase 25,000 shares of common stock resulted in a charge to operations of $63,000. In addition, the Company recognized a liability and related charge to operations of $354,000 related to Dr. Cooper's cash severance, consulting agreement cash compensation and COBRA premiums in 2012. Such liability was paid in full as of December 31, 2013.

Bobby W. Sandage

In addition, on December 28, 2012, Dr. Bobby W. Sandage, Jr. became President of the Company. Dr. Sandage's 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 $286,000 of the severance obligation as of December 31, 2013.

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.

16. 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 $41.1 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,	
	2013	2012
($ in thousands)		
Deferred tax assets:		
Net operating loss carryforwards	$ 31,450	$ 19,572
Amortization of up-front fees	2,865	3,087
Amortization of in-process R&D	460	407
Stock compensation	2,827	1,522
Accruals and reserves	854	622
Tax credits	2,686	991
Total deferred tax assets	41,142	26,201
Valuation allowance	(41,142)	(26,201)
Net deferred tax assets	$ —	$ —

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

	For the Year Ended December 31,		
	2013	2012	2011
Percentage of pre-tax income:			
U.S. federal statutory income tax rate	35 %	35 %	35 %
State taxes, net of federal benefit	4 %	4 %	5 %
Acquired NOL	—	—	9 %
Credits	4 %	1 %	2 %
Non-deductible items	(2)%	(2)%	(21)%
Other (1)	(1)%	(5)%	(2)%
Change in valuation allowance	(40)%	(33)%	(28)%
Effective income tax rate	0 %	0 %	0 %

(1) – Other consists of: in 2013 state NOL true-up (1%), in 2012 state rate change (2%) and state NOL true up (3%) and in 2011, prior year NOL true-up (3%) and state rate change 1%.

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, 2013 and 2012. Management reevaluates the positive and negative evidence at each reporting period.

In 2012, the Company identified an error related to the taxation of the 2011 Asphelia Asset Purchase. The Company accounted for the transaction as a taxable asset purchase in 2011 but during 2012 determined that the transaction should have been accounted for as a non-taxable reorganization under IRC 368 (a)(1)(c). The net impact of the error was to overstate gross deferred tax assets by $3.6 million and overstate the valuation allowance by $3.6 million with no impact to net deferred tax assets or the provision for income taxes in the schedules below. The error had no effect on the Company's consolidated balance sheets, statements of operations, changes in stockholders' deficit or cash flows for any period presented. As a result, management believes the impact of this error is immaterial to previously issued financial statements. The 2011 amounts presented in the tax footnote herein have been revised to correct for this immaterial misstatement.

As of December 31, 2013, the Company has federal net operating loss carryforwards and research and development tax credit carryforwards of approximately $87.6 million and $2.7 million, including an orphan drug tax credit of $1.3 million, respectively, which expire beginning in 2026 and 2029, respectively. As of December 31, 2013, the Company has state net operating loss carryforwards of approximately $35.2 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 $2.7 million of the federal net operating loss carryforward and $1.5 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, 2013, 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, 2013. The tax years 2006 through 2013 remain open to examination by one or more major taxing jurisdictions to which the Company is subject.

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, in the amount of $329,000.

17. Subsequent Events

Executive Officer and Board of Directors Matters

Kevin Horgan

Effective January 28, 2014, Dr. Kevin Hogan, our Chief Medical Officer, was separated from service from the Company. The Company will pay him $340,000 in severance.

Michael Weiss

Mr. Michael Weiss has served as a director of our Company since December 19, 2013 and from that time until February 19, 2014 served as the Co-Vice Chairman of our 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 Dr. Weiss addressing his officer positions with the Company and the Company will pay Mr. Weiss an annual base salary of $28,275, the lowest salary permissible under New York State law. Mr. Weiss will also be eligible for a discretionary bonus based on his achievement of performance goals and objectives as established by our 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. 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. Such shares shall vest at a rate of 16.67% for the first three annual anniversaries and 10% will vest, in five equal installments upon certain events occurring.

Malcolm Hoenlein

On February 20, 2014, the Company appointed Mr. Malcolm Hoenlein to the vacant seat on its board of directors. Mr. Hoenlein was granted 30,000 shares of restricted stock vesting one-third on each annual anniversary of grant.

Strategic Transaction Committee

On February 20, 2014, The Company established a Strategic Transaction Committee of the board of directors. Messrs Lobell, Rowinsky, Harvey and Barrett were appointed 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.

IDB Note

On February 13, 2014, the Company executed a Promissory Note (the "Note") with Israel Discount Bank of New York (the "Bank") in the amount of $15.0 million. The Company used certain proceeds from the Note to repay its prior loan from Hercules Technology Growth Capital, Inc. and fund its general working capital needs. The Company may request revolving advances under the Note in a minimum amount of $100,000 (or the remaining amount of the undrawn balance under the Note if such amount is less than $100,000). All amounts advanced under the Note are due in full at the earlier of: (i) February 13, 2016, or (ii) on the Bank'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 Note contains various representations and warranties customary for financings of this type.

The obligations of the Company under the 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 Note, recover from the money market account all amounts outstanding under the Note. The Pledge Agreement contains various representations, warranties, and covenants customary for pledge agreements of this type.

The Company will default on the 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 Note, the Bank may: (i) declare the entire outstanding principal balance of the Note, together with all accrued interest and other sums due under the 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 Payoff

On February 13, 2014, the Company repaid its Hercules Note in full. Early Payment of the 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.

18. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for fiscal years 2013 and 2012. 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
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)
2012				
Operating expenses	$ (6,581)	$ (6,465)	$ (5,831)	$ (8,299)
Other income/(expense)	$ 25	$ 10	$ (104)	$ (365)
Net loss	$ (6,556)	$ (6,455)	$ (5,935)	$ (8,664)
Basic and diluted net loss per common share	$ (0.35)	$ (0.34)	$ (0.24)	$ (0.36)

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 14, 2014

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 14, 2014
/s/ Lucy Lu, M.D. Lucy Lu, M.D.	Executive Vice President and Chief Financial Officer (*principal financial officer*)	March 14, 2014
/s/ Eric K. Rowinsky, M.D. Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	March 14, 2014
/s/ Michael S. Weiss Michael S. Weiss	Executive Vice Chairman, Strategic Development and Director	March 14, 2014
/s/ David J. Barrett David J. Barrett	Director	March 14, 2014
/s/ Jimmie Harvey, Jr., M.D. Jimmie Harvey, Jr., M.D.	Director	March 14, 2014
/s/ J. Jay Lobell J. Jay Lobell	Director	March 14, 2014
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 14, 2014

[This page intentionally left blank.]

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, 2013 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 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 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 14, 2014

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, 2013 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 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 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 14, 2014

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, 2013, 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 14, 2014

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, 2013, 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 14, 2014

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

24 New England Executive Park, Suite 105
Burlington, Massachusetts 01803

Phone: (781) 652-4500
Fax: (781) 652-4545
www.coronadobiosciences.com