2012 Annual Report

Included in the 2012 Annual Report:
Form 10-K filed with the U.S. Securities and Exchange Commission on
March 18, 2013

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, 2012

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from to

Commission File No. 001-35366

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

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter: Not applicable.

As of March 11, 2013, there were 26,023,484 shares of the registrant's common stock outstanding.

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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," "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:

- 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

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

TSO

TSO, or CNDO-201, is a biologic comprising *Trichuris suis* ova, the microscopic eggs of the porcine whipworm, which we believe could be used for the treatment of a range of autoimmune diseases, such as Crohn's disease, or Crohn's, ulcerative colitis, or UC, multiple sclerosis, or MS, autism, psoriasis, Type 1 diabetes, or T1D, psoriatic arthritis and rheumatoid arthritis. In February 2012, we announced positive results from our Phase 1 clinical trial of TSO in 36 patients with Crohn's. The trial was a sequential dose-escalation, double-blind, placebo-controlled study to examine safety and tolerability. TSO was shown to be safe and well tolerated, with no serious treatment-related adverse events reported. To date, a number of investigator-sponsored clinical trials have been conducted using TSO in patients suffering from Crohn's, UC or MS. These studies also demonstrated that TSO is safe and well tolerated.

In April 2012, our development partner, Dr. Falk Pharma GmbH, or Falk, reported that an independent data monitoring committee had found no safety concerns and a positive efficacy trend in an interim analysis (blinded to Falk) of clinical data from the initial 120 patients in Falk's ongoing Phase 2 clinical trial in Europe evaluating TSO in Crohn's patients, known as TRUST-II. Based on the committee's recommendations, Falk has advised us that it is increasing the size of its trial and will conduct a subsequent interim analysis at the time the trial reaches approximately 240 patients, which we expect to occur in the second half of 2013.

In August 2012, we initiated in the U.S. a Phase 2 clinical trial of TSO, known as TRUST-I, designed to evaluate the safety and efficacy of TSO in approximately 220 patients with Crohn's and expect to have initial study results in the second half of 2013.

We have the exclusive rights to TSO in North America, South America and Japan (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 to us the exclusive right to manufacture TSO for the Coronado Territories in exchange for certain consideration to Ovamed. We anticipate that we will continue to purchase our Phase 2 TSO supplies and we may purchase at least a portion of our Phase 3 TSO supplies from Ovamed under the current agreement. Thereafter, we plan to manufacture our remaining Phase 3 supplies from our US facility which we plan to establish in Woburn, MA under a lease acquired from Ovamed as part of the agreement.

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

CNDO-109

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

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 Crohn's and UC, MS, autism, psoriasis, T1D and psoriatic and rheumatoid arthritis.

According to a 2012 *Decision Resources* report, in the United States and Japan, the estimated prevalence of Crohn's was 534,000 patients, UC was 669,000 patients and MS was 485,000 patients (Tim to update market data). 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. Per the National Psoriasis Foundation, approximately 1 million Americans have psoriatic arthritis. Rheumatoid arthritis, or RA, affects more than 2 million people in the United States. 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.

Crohn's is characterized by inflammation of the gastrointestinal tract that causes painful and debilitating symptoms. Most patients with Crohn's 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 Crohn's 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.

Psoriatic arthritis (also arthritis psoriatica, arthropathic psoriasis or psoriatic arthropathy) is a type of inflammatory arthritis that may develop in up to 30 percent of people who have psoriasis. Psoriatic arthritis is said to be a seronegative spondyloarthropathy and therefore occurs more commonly in patients with tissue type HLA-B27. Symptoms involve pain and inflammation, as well as extreme exhaustion that does not go away with adequate rest. The exhaustion may last for days or weeks without abatement. Psoriatic arthritis may remain mild, or may progress to more destructive joint disease. Periods of active disease, or flares, will typically alternate with periods of remission. Treatments are directed at reducing and controlling inflammation. Milder cases of psoriatic arthitis may be treated with Non-Steroidal Anti-Inflammatory Drugs, or NSAIDs alone; however, there is a trend toward earlier use of disease modifying antirheumatic drugs or biological response modifiers to prevent irreversible joint destruction.

RA is a long-term autoimmune disease that leads to inflammation of the joints and surrounding tissues. It can also affect other organs. RA usually affects joints on both sides of the body equally. Wrists, fingers, knees, feet, and ankles are the most commonly affected. The disease often begins slowly, usually with only minor joint pain, stiffness, and fatigue. RA usually requires lifelong treatment, including medications (biologics and immunosuppressants), physical therapy, exercise, education, and possibly surgery. Early, aggressive treatment for RA can delay joint destruction.

Since many autoimmune diseases are being diagnosed in younger patients, the impact of long-term medical treatment, including dosing convenience and safety, is becoming increasingly important.

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 Product Candidates

TSO

TSO is a biologic product candidate for the treatment of autoimmune diseases. We initially plan to investigate TSO for the treatment of Crohn's, UC, MS, autism, psoriasis, T1D, psoriatic arthritis and RA. TSO 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 such as IBD, specifically Crohn's and UC. Dr. Weinstock has discovered that when the microscopic eggs of a certain helminth, preferably *T. suis*, the porcine whipworm, are administered to patients with IBD a beneficial immune response is induced, which provides clinical benefit to the underlying disease with minimal side-effects. Dr. Weinstock is a consultant to us and a member of our scientific advisory board and certain of his colleagues, namely David Elliott, M.D., Ph.D., and William Sanborn, M.D. are also consultants to us.

Background

The use of helminths in the treatment of autoimmune disease is based on the belief that the immune systems of populations living in the relatively sterile environments found in developed countries with little or no exposure to parasites may develop in abnormal ways. 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 IBD 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. Conversely, the incidence of IBD is rare in less developed countries and in persons with blue-collar jobs involving exposure to dirt and physical exercise.

In contrast to the epidemiologic findings of IBD, according to articles by Dr. Weinstock and others published in the *New England Journal of Medicine* in 2002 and the *International Journal for Parasitology* in 2007, the prevalence of helminths is highest in warm climates and in populations characterized by crowding, poor sanitation, and impure food supply. Furthermore, the incidence of IBD 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 for IBD 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.

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 in the *American Journal of Gastroenterology* in 2005, 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

The initial safety and efficacy of TSO in Crohn's has been evaluated in two open-label investigator-sponsored clinical trials. The first, a pilot clinical trial conducted by Dr. Weinstock and his colleagues and reported in the *American Journal of Gastroenterology* in 2003, administered a single dose of 2500 embryonated TSO orally to four patients with refractory Crohn's. Patients were followed every two weeks for at least 12 weeks, with the efficacy of therapy determined by the Crohn's Disease Activity Index, or CDAI and the Inflammatory Bowel Disease Quality of Life questionnaire, or IBDQ. Using an IBDQ score > 170 to indicate remission, three of four (75%) patients achieved remission by week 8. Similarly, three of four (75%) patients achieved remission during the observation period as assessed by a CDAI < 150. However, two of the three patients who achieved remission relapsed at the end of the 12-week observation period. No significant clinical complications or adverse events occurred in any of the patients in this study.

In a subsequent open-label clinical trial reported in *GUT* in 2005, Dr. Weinstock and his colleagues examined the safety and efficacy of TSO in 29 patients with active Crohn's, defined by a CDAI > 220. Patients received TSO in individual aliquots of 2500 ova suspended in a solution every three weeks for 24 weeks. Patients maintained diaries of clinical symptoms, and disease activity was measured by CDAI. Therapy with TSO was associated with substantial and sustained improvement, with 79.3% patients experiencing a response (decrease in CDAI > 100 points or CDAI < 150) and 72.4% achieving remission (CDAI < 150) at week 24. TSO was well tolerated. No significant clinical complications or adverse events occurred in any of the patients in this study.

Falk is currently conducting a Phase 2 double-blind, randomized, placebo-controlled, multi-center trial in Europe evaluating the efficacy and safety of TSO in Crohn's. The second interim analysis is expected by the end of 2013. In March 2012, we signed a Collaboration Agreement with Falk and Ovamed for the development of TSO in Crohn's.

Two investigator-sponsored studies of TSO have been conducted in patients with UC. The first study was a pilot study conducted by Dr. Weinstock and his colleagues and published in the *American Journal of Gastroenterology*, in 2003 in which three patients with refractory UC were treated with a single dose of 2500 embryonated *T. suis* eggs orally and observed every two weeks for 12 weeks. The IBDQ and Simple Clinical Colitis Activity Index, or SCCAI, were used to determine the efficacy of therapy. Using an IBDQ score > 170 to define remission, all three patients achieved remission by week eight. Using an SCCAI < 4 to indicate remission, each of the UC patients achieved remission during the treatment and observation period, and one patient experienced a relapse. No significant clinical complications or adverse events occurred in any of the patients in this study.

As reported in the *American Journal of Gastroenterology* in 2005, Dr. Weinstock and his colleagues subsequently conducted a randomized, double-blind, placebo-controlled clinical trial to determine the safety and efficacy of TSO in 54 patients with active UC (defined by an Ulcerative Colitis Disease Activity Index, or UCDAI, > 4) who were treated with placebo or 2500 TSO every two weeks for 12 weeks. After the first 12 weeks of treatment, placebo-treated patients were switched to TSO for a second 12-week interval and TSO patients were switched to placebo. The blind was maintained during the crossover phase. In order to calculate UCDAI and SCCAI scores, patients kept diaries detailing their clinical symptoms. The primary measure of efficacy was clinical improvement at 12 weeks, defined as a decrease in UCDAI > 4. Clinical remission, defined as UCDAI < 2, was a secondary endpoint. Of the 54 patients enrolled in the study, 24 received placebo and 30 received TSO during the first 12 weeks of the study. The proportion of patients achieving a favorable response was significantly higher with TSO compared with placebo in both the intention-to-treat, or ITT, (43.3% vs. 16.7%, p = 0.04) and per protocol, or PP, (44.8% vs. 17.4%, p = 0.04) populations. Only patients with active disease (UCDAI > 4) were included in the analysis of the crossover phase of the study. Among 31 patients (n=15 for placebo, n=16 for TSO) analyzed, the percentage of TSO-treated patients achieving response was higher than that for placebo-treated patients (56.3% vs. 13.3%, p = 0.02). When the two study periods were combined, TSO administration was associated with significantly higher responses in both the ITT and PP populations. No significant clinical complications or adverse events occurred in any of the treated patients in this study.

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.

There are also additional ongoing or proposed investigator-initiated clinical trials evaluating TSO in various indications, including UC, MS, autism, psoriasis, T1D, psoriatic arthritis, and RA. 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 one 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 also plan to initiate additional trials in other indications, including additional sites for the psoriasis trial, autism, psoriatic arthritis, and T1D over the next 12 months. 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 Crohn's 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 Crohn's 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. Dr. Elliot is a consultant to us.

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

In April 2012, we received from Falk a recommendation from the independent data monitoring committee that conducted an interim analysis (blinded to Falk) of clinical data from the initial 120 patients in Falk's Phase 2 clinical trial in Europe evaluating TSO in Crohn's. The committee noted no safety concerns and a positive efficacy trend in its recommendation that the study continue. Falk advised us that they are adopting the

committee's recommendations to increase the sample size and to conduct a subsequent interim analysis at the time the trial reaches approximately 240 patients. The Falk Phase 2 clinical trial, known as TRUST-II, was initially expected to enroll approximately 212 patients and to evaluate three different dosages of TSO versus placebo. The interim analysis aimed to verify the assumptions of the sample size calculation or to recalculate sample size based on the effect size estimations of the interim analysis, as well as evaluating whether to discontinue one or two of the active treatment arms. Based on currently projected enrollment rates, we expect the additional analysis to occur in the second half of 2013.

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 Crohn's, and expect to have initial study results in the second half of 2013.

In addition, we plan to conduct pilot studies and support certain investigator initiated clinical trials in various other autoimmune diseases. In close collaboration with investigators at NYU and Montefiore, two trials were initiated, one in UC and one in autism, respectively. The UC trial at NYU, led by Drs. Poles, Wolff and Loke, is a primarily mechanism of action trial, including 18 patients, treated with TSO at 2500 ova every second week, for 3 months, followed by a wash-out period and then the patients on TSO will receive placebo and vice versa. Colonoscopies are performed at baseline to characterize the microbe, then again at the end of 12 weeks of treatment of either placebo or TSO (2500 ova). The primary endpoint is the amount of mucus production, but there will also be measurements of clinical efficacy. The adult autism trial at Montefiore, led by Dr. Hollander, is an initial attempt to study the effect of TSO (2500 ova every 2 weeks) on some of the symptoms of autism addressing the immune basis of the disease. It is a small study, in 10 patients, over a period of 12 weeks, followed by a period of 12 weeks when patients cross-over to drug or placebo respectively. The primary outcome includes three different autism scales, Autism Behavior Checklist, Clinical Global Impression, and Yale-Brown Obsessive Compulsive scale.

The NIH UC trial is a 120 patient randomized, double-blind, study comparing the change in clinical symptoms of ulcerative colitis (using the ulcerative colitis disease activity index) following 12 weeks of treatment of either placebo or TSO (7500 ova).

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 will be subject to an FDA inspection to assess compliance with FDA standards and is subject to EMA inspections to assess compliance with EMA standards. See "Government Regulation and Product Approval".

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 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 intend to establish a TSO manufacturing facility. Build out and site preparation of the manufacturing facility are planned to commence in the first half of 2013 and continue throughout the year to enable production of Phase 3 supplies of TSO. Ovamed agreed to assist us in establishing this 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 the parties. This facility will be required to meet GMP standards and will be subject to FDA and other regulatory authorities' inspections.

CNDO-109

CNDO-109 is a lysate (disrupted CTV-1 cells, cell membrane fragments, cell proteins and other cellular components) that activates donor NK cells. CTV-1 is a leukemic cell line recently 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 therapies, 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 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 most 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 eight 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.

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 MRD in AML patients with relapsed/refractory disease. In Phase 1/2 oncology clinical trials, dose limiting toxicity stopping rules are commonly applied. The CNDO-109 Phase 1/2 trial is subject to a set of Dose-Limiting Toxicities, or DLTs, that could suspend or stop dose escalation by predetermined criteria, including allergic reactions, prolonged aplasia or other organ toxicities of a serious nature. We are also considering participation in a Phase 1/2 multiple myeloma trial 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 relating to TSO, Asphelia assigned the Exclusive Sublicense Agreement, dated December 2005, between Asphelia and Ovamed, as amended, or the Ovamed License, and Manufacturing and Supply Agreement, dated March 2006, between Asphelia Pharmaceuticals, Inc., or Asphelia, and Ovamed, as amended, or 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 make, 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 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 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 (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 intend to establish a TSO manufacturing facility. Build out of the manufacturing facility will commence in early 2013 and continue throughout the year. Ovamed agreed to assist us in establishing this 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 the parties.

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 Crohn's. 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 Crohn's, 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 Crohn's 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 by the first half of 2014, 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 Crohn's, under which we and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn's in the United States and Europe and will share in certain pre-clinical development costs.

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 $843,000, 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, which we refer to as the LSA, with Ovamed GmbH, or 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.

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 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. 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.

The agreement 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, or the PCT agreement, with PCT pursuant to which PCT may, from time to time, 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 development of manufacturing processes for CNDO-109 under the PCT agreement. We pay for services under the PCT 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 PCT agreement are owned solely and exclusively by and assigned to us. Through December 31, 2012, we have entered into statements of work with PCT aggregating $2.7 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 Crohn's 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. Patent No. 8,257,970 and pending United States Patent Application Serial No. 13/601,153 and the corresponding national phase applications filed in

Australia, Canada, Europe, India 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 Crohn's, 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 Crohn's, 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 ALL, Eisai Corporation's Dacogen (decitabine), currently approved as a treatment for Myelodysplastic Syndromes, or MDS, Celgene Corporation's Vidaza (azacitidine), currently approved as a treatment for MDS, and Vion Pharmaceuticals, Inc.'s Onrigin (laromustine) 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 2013, 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 in which we intend to establish a TSO

manufacturing facility. Build out and site preparation of the manufacturing facility are planned to commence in the first half of 2013 and continue to enable production of Phase 3 supplies of TSO. Ovamed agreed to assist us in establishing this 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 the parties.

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. We intend to request orphan drug designation for CNDO-109 for the treatment of AML. 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, 2012, we had 16 full time employees.

Available Information

Our website address is www.coronadobiosciences.com. We make available, free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as is reasonably practicable after such material is electronically filed with, or furnished to, the SEC, but other information on our website is not incorporated into this report. The SEC maintains an internet site that contains these reports at www.sec.gov.

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 Business and Industry

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

We are a clinical development stage biopharmaceutical company. We have engaged primarily in research and development activities since inception, have not generated any revenues from product sales and have incurred significant net losses since our inception. As of December 31, 2012, we had an accumulated deficit of approximately $84.2 million. We have not demonstrated our ability to perform the functions necessary for the successful commercialization of any of our products. The successful commercialization of any of our products will require us to perform a variety of functions, including:

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

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

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

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

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

All of our product candidates, including related intellectual property rights, were in-licensed from third parties. Under the terms of our license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach by us. Our licenses require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments depends on our ability to generate cash in the future. These agreements generally require us to use diligent and reasonable efforts to develop and commercialize the product candidate. In the case of TSO, Ovamed licenses TSO from a third party, University of Iowa Research Foundation, or UIRF, in exchange for annual and milestone payments, patent cost reimbursement,

royalties based on sales and diligence obligations. Our rights to TSO are, therefore, also subject to Ovamed's performance of its obligations to UIRF, any breach of which we may be required to remedy in order to preserve our rights.

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

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

Pharmaceutical development has inherent risk. We will be required to demonstrate through well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later 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.

We currently rely completely on Ovamed, and other third parties to manufacture our preclinical and clinical pharmaceutical supplies of TSO. We plan to establish a U.S. manufacturing facility to manufacture Phase 3 clinical supplies and commercial supplies of TSO. Our dependence on third party suppliers or our inability to successfully produce TSO could adversely impact our business.

We currently 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 would materially adversely affect clinical development and potential commercialization of the product. In the event that the FDA or such other agencies determine that we, Ovamed or 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 NDO-109 on a timely basis or at all.

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

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

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

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

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

noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

biotechnology and pharmaceutical companies, as well as universities and research organizations. If we are not able to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

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

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

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

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

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

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

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

- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;

- our competitors, many of which have substantially greater resources than we or our partners and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products;
- there may be significant pressure on the 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 United States Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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

Our success also depends 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 $10.0 million, $36.4 million and $27.6 million for the years ended December 31, 2010, 2011 and 2012, respectively. At December 31, 2012, we had an accumulated deficit of approximately $84.2 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant or any revenues or if we will ever achieve or sustain profitability.

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

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

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2010, 2011 and 2012 we incurred research and development expenses of approximately $8.3 million, $8.6 million and $17.5 million, respectively. Since our inception in 2006, we incurred research and development expenses of approximately $42.0 million. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates, establishing manufacturing capabilities for TSO in the United States, and purchasing clinical trial materials from our suppliers. We believe that our current cash will be sufficient to meet our anticipated cash requirements through the first quarter of 2014 and that we will require substantial additional funds to support our continued research and development activities, including costs of preclinical studies and clinical trials, obtaining regulatory approvals and potential commercialization and for the payment of principal and interest under our existing loan agreement. We have based this 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 be required to report on, and our independent registered public accounting firm is required to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, or the Exchange Act, we may need to further upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. If material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

Risks Associated with our Capital Stock

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

At December 31, 2012, Lindsay A. Rosenwald, M.D., a member of our board of directors, beneficially owned approximately 14.72% of our issued and outstanding capital stock. By virtue of his holdings and his membership on our board of directors, Dr. Rosenwald may influence the election of the members of our board of directors, our management and our affairs and may make it difficult for us to consummate corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders. In addition, Dr. Rosenwald is an affiliate of National Securities Corporation, or National, which acted as an underwriter of our June 2012 public offering of common stock. National received related commissions of $187,000 in connection with the offering. Dr. Rosenwald purchased at the public offering price 200,000 shares of common stock in the offering.

In connection with our Series C Financing in 2011, National received commissions of $2.6 million and five-year warrants to purchase an aggregate of 461,263 Series C shares at an exercise price of $5.59, which were subsequently transferred by National to other individuals and entities and are now exercisable to purchase 458,276 shares of common stock.

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

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

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

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

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

Almost all of our 24.4 million outstanding shares of common stock as of December 31, 2012, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, or an effective registration statement. In addition, we recently filed a shelf registration statement on Form S-3 in September 2012, 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 in the first quarter of 2013, through March 11, 2013 we sold 1,426,250 shares of our common stock resulting in net proceeds to us of $10.5 million pursuant to this Form S-3.

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 extends 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 will be recognized in the period of enactment, which is 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, Massachusetts 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 expects to occupy the space in the second half of 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

Our common stock is listed for trading on The NASDAQ Capital Market, or NASDAQ, under the symbol "CNDO." From November 17, 2011 to December 16, 2011, our common stock was traded in the over-the-counter market and quoted through the Over-The-Counter Bulletin Board, or OTCBB, under the same symbol. The following table sets forth the high and low bid prices for our common stock from November 17, 2011, the date trading of our common stock commenced, to December 16, 2011 as reported by the OTCBB, and the high and low sale prices for our common stock from December 19, 2011 through December 31, 2012, as reported by NASDAQ. The OTCBB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

	2012		2011 [(1),(2)]	
	High	Low	High	Low
First quarter	$9.52	$5.00	N/A	N/A
Second quarter	$8.50	$4.93	N/A	N/A
Third quarter	$6.92	$5.20	N/A	N/A
Fourth quarter	$5.97	$4.36	$6.50	$6.00

(1) – December 19, 2011 through December 31, 2011.
(2) – November 17, 2011 to December 16, 2011 reported on OTCBB. The high and low bid prices for such period were $9.50 and $6.00, respectively.

Holders of Record

As of March 10, 2013, there were 679 holders of record of our common stock.

Repurchases

None.

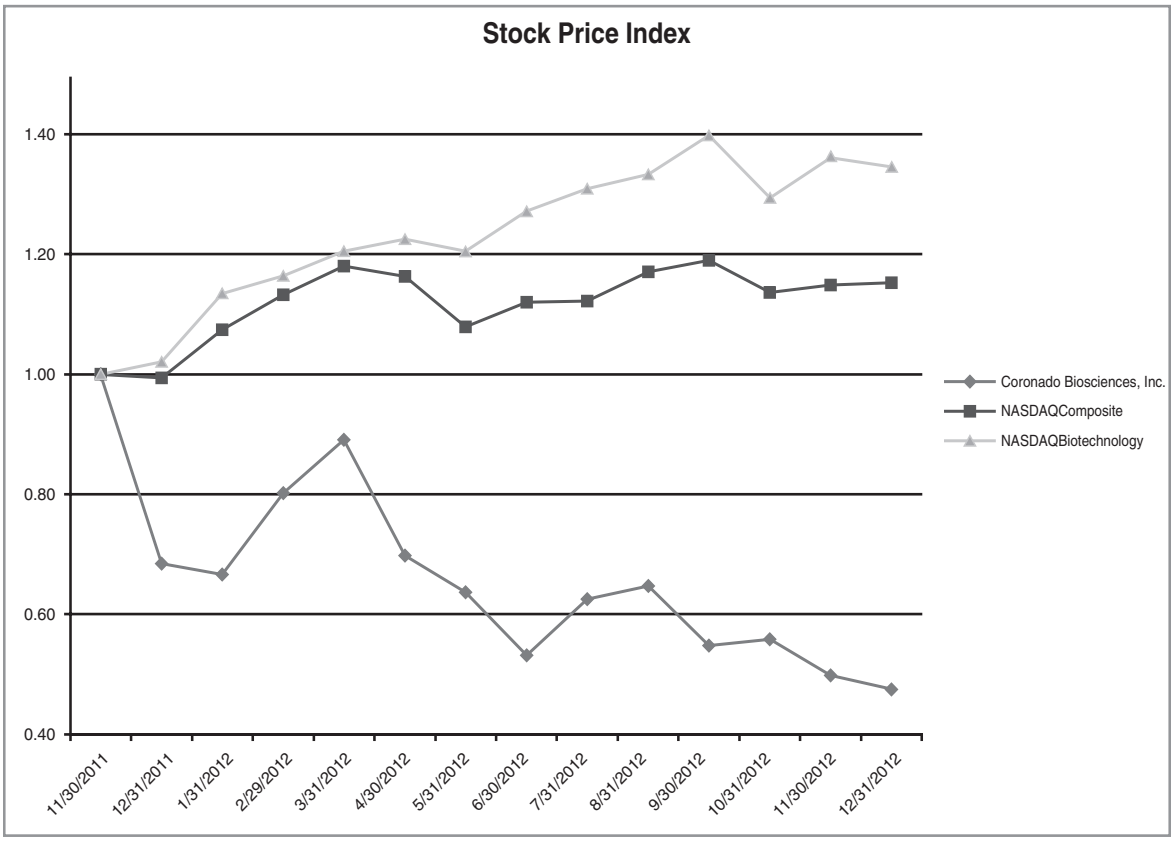
Dividends

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.

Securities Authorized for Issuance under Equity Compensation Plans

See "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for a discussion of our equity compensation plans.

Coronado Biosciences, Inc.
Stock Price Index Chart
As of December 31, 2012



(1)

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

Item 6. Selected Consolidated Financial Data.

(In thousands except per share amounts)	For the Years Ended December 31, 2012	2011	2010	2009	2008
Operating expenses:					
Research and development	$ 17,468	$ 8,583	$ 8,341	$ 2,270	$ 2,895
General and administrative	8,665	5,755	900	343	348
In-process research and development	1,043	20,706	—	—	—
Loss from operations	(27,176)	(35,044)	(9,241)	(2,613)	(3,243)
Interest income	236	165	61	—	18
Interest expense	(670)	(74)	(1,535)	(1,053)	(573)
Other income	—	—	733	—	—
Warrant expense	—	(1,407)	—	—	—
Net loss	(27,610)	(36,360)	(9,982)	(3,666)	(3,798)
Common Stock dividend to Series A Convertible Preferred Stockholders	—	(5,861)	—	—	—
Net loss attributed to Common Stockholders	$ (27,610)	$ (42,221)	$ (9,982)	$ (3,666)	$ (3,798)
Basic and diluted net loss per common share	$ (1.27)	$ (5.51)	$ (2.24)	$ (1.01)	$ (1.39)
Weighted average common shares outstanding—basic and diluted	21,654,984	7,662,984	4,453,786	3,612,769	2,731,212
Financial Condition:					
Cash	$ 40,199	$ 23,160	$ 14,862	$ 1,510	$ 7
Total assets	$ 40,992	$ 23,375	$ 14,939	$ 1,687	$ 461
Current liabilities	$ 5,132	$ 3,493	$ 1,559	$ 11,207	$ 6,964
Notes payable and other, net of current portion	$ 13,827	$ 750	$ —	$ 570	$ —
Stockholders' equity/(deficit)	$ 22,033	$ 19,132	$ (15,897)	$ (10,090)	$ (6,503)

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

We are a clinical stage biopharmaceutical company focused on the development of novel immunotherapy biologic agents for the treatment of autoimmune diseases and cancer. Our two principal pharmaceutical product candidates 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, ulcerative colitis, multiple sclerosis, autism, psoriasis, type 1 diabetes and rheumatoid arthritis; 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 Pharmaceuticals, Inc., or 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 PCP in the aggregate principal amount of $750,000, 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, Massachusetts, where we intend to establish a TSO manufacturing facility. Build out of the manufacturing facility are planned to commence in 2013 and continue throughout the year to enable production of supplies of TSO, for use in Phase 3 clinical trials. Ovamed agreed to assist us in establishing this 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 Crohn's disease. 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 Crohn's disease, 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 Crohn's disease 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, 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 Crohn's disease, 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 Crohn's disease in the United States and Europe and will share in certain pre-clinical development costs.

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.

In September 2012, the Company filed a shelf registration statement on Form S-3 pursuant to which the Company may sell up to $75.0 million of common stock over the next three years. In October 2012, the Company entered into an At Market Issuance Sales Agreement, or ATM with MLV & Co. LLC, or MLV, to issue and sell up to $30.0 million of common stock. Under the terms of the ATM we pay directly to MLV fees equal to 3% of the gross proceeds. Through December 31, 2012, the Company sold 3,361 shares of common stock for net proceeds of $19,000. From January 1, 2013 through March 11, 2013, the Company issued 1,426,250 shares of common stock pursuant to the ATM and received net proceeds of $10.5 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 remains a member of the Board of Directors. (See note 15 of Notes to Consolidated Financial Statements.)

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations 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, 2012 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 taking the average historic 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. We did not rely on implied volatilities of traded options in our industry peers' common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, 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, 2012, 2011, and 2010, stock-based compensation expense was $3.6 million, $1.5 million, and $2.3 million, respectively. As of December 31, 2012, we had approximately $4.5 million of total unrecognized compensation expense, related to unvested stock options and warrants granted to employees and non-employees, which we expect to recognize over a weighted-average period of approximately 1.4 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.

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, 2012, we had an accumulated deficit of $84.2 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 from our 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, 2010, 2011 and 2012 research and development expenses were $8.3 million, $8.6 million and $17.5 million, respectively, and such expenses were $42.0 million for the period from inception (June 28, 2006) to December 31, 2012. Noncash, stock-based compensation expense included in research and development in 2012 and from inception through 2012 was $3.6 million and $7.5 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 substantial expenses related to our research and development activities for the foreseeable future as we continue product development. 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, 2012, direct, external development costs incurred for our TSO product development program were $13.8 million, including $0.2 million, $2.7 million and $10.9 million for the years ended December 31, 2010, 2011 and 2012, 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, 2012, direct, external development costs incurred for our CNDO–109 product development program were $6.2 million, including $2.1 million, $1.9 million and $1.9 million, for the years ended December 31, 2010, 2011 and 2012, respectively. Our results of operations for the years ended

December 31, 2010 and 2011 include direct, external development costs incurred in connection with two product development programs that have been discontinued. From inception through December 31, 2012, such expenses totaled $5.2 million. No costs were incurred for these programs in 2012.

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, 2012, G&A expenses were $16.3 million, including $0.9 million, $5.8 million, and $8.7 million for the years ended December 31, 2010, 2011 and 2012, respectively. Non cash, stock-based compensation expense included in general and administrative in 2012 and from inception through 2012, was $3.6 million and $7.5 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, 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). 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.

Comparison of Years Ended December 31, 2011 and 2010

	For the year ended December 31,		Variance	
	2011	2010	$	%
Operating expenses:				
Research and development	$ 8,583	$ 8,341	$ 242	3%
General and administrative	5,755	900	4,855	539%
In-process research and development	20,706	—	20,706	NM
Loss from operations	(35,044)	(9,241)	25,803	279%
Interest income	165	61	104	170%
Other income	—	733	(733)	NM
Interest expense	(74)	(1,535)	(1,461)	(95)%
Warrant expense	(1,407)	—	1,407	NM
Net loss	$(36,360)	$(9,982)	$26,378	264%

NM–Not meaningful

Research and development expenses increased $242,000, or 3%, from the year ended December 31, 2010 to the year ended December 31, 2011. This increase was primarily due to $2.5 million of external development costs related to TSO, including a milestone-related charge of $1.5 million recognized in connection with the filing of an IND for TSO and $0.6 million of increased consulting expenses, severance-related costs, and other general expenses, primarily offset by a $1.4 million decrease in stock-based compensation expense related to the 2010 vesting of restricted common stock issued to non-employees in 2007, a $1.2 million decrease in development costs related to discontinued product candidates and a $0.3 million decrease in CNDO–109 development costs. General and administrative expenses increased $4.9 million from the year ended December 31, 2010 to the year ended December 31, 2011, reflecting a substantial increase in the level of our business activity during 2011 and transition to a public company. The increase in G&A expenses to support these activities consisted primarily of a $1.9 million increase in professional fees, consisting of legal and accounting fees, a $1.3 million increase in personnel costs, a $0.5 million increase in stock compensation expense, and a $0.4 million increase in expenses relating to consulting and outside services.

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 $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 2011, we incurred interest expense of $74,000 related to the PCP Note. Interest expense of $1,535,000 in 2010 related to an aggregate of $9.9 million of debt, which was either repaid or converted to our Series A Shares between April 2010 and December 2010.

The increase in interest income in 2011 compared to 2010 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

At December 31, 2012, we had cash and cash equivalents of $40.2 million. To date, we have funded our operations through the sale of debt and equity securities aggregating $93.3 million of net proceeds. As of December 31, 2010, all notes and other debt then-outstanding were either repaid or converted into our Series A Shares. In September 2012, we repaid the $750,000 PCP Note. As of December 31, 2012 and 2011, 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. From January 1, 2013 through March 8, 2013, we issued 1,426,250 shares of common stock pursuant to the Sales Agreement and received net proceeds of $10.5 million. We intend to continue to utilize this financing vehicle at opportune times during 2013.

We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates. We will require additional financing to develop our product candidates, prepare regulatory filings and obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. We believe that our current cash and cash equivalents are sufficient to fund operations through the first quarter of 2014 based on our current business plan. 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. If needed, we will seek to raise capital through additional 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 us on acceptable terms or at all. If adequate funds are not available to us, we may be required to delay, curtail or eliminate one or more of our research and development programs.

Cash Flows for the Three Years Ended December 31, 2012, 2011 and 2010

	For the Year Ended December 31,		
(In thousands)	**2012**	**2011**	**2010**
Statement of Cash Flows Data:			
Total cash provided by (used in):			
Operating activities	$(23,194)	$(10,952)	$ (5,677)
Investing activities	(279)	(3,843)	(13)
Financing activities	40,512	23,093	19,042
Increase in cash and cash equivalents	$ 17,039	$ 8,298	$13,352

Operating Activities

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 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.

Net cash used in operating activities increased $5.3 million from the year ended December 31, 2010 to the year ended December 31, 2011. The increase in net loss of $26.4 million, included a $1.4 million increase in the fair market value of the Series C warrant liability and a $1.9 million increase in accounts payable and accrued expenses, which were offset by $20.7 million of noncash expense for in-process research and development in connection with our acquisition of certain rights related to TSO, a $0.9 million decrease in stock-based compensation and a $0.8 million decrease in the change in fair value of a warrant-embedded conversion feature.

Investing Activities

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 $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.

Cash provided by financing activities of $19.0 million in the year ended December 31, 2010 primarily reflects our issuance of the Series A Shares for net proceeds of $19.4 million.

Contingent Contractual Payments

The following table summarizes our contractual obligations as of December 31, 2012, 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)	$18,221	$ 3,184	$15,037	$ —	$ —
Operating leases (2)	1,559	709	423	407	20
Annual license fees (3)	8,750	250	5,250	1,500	1,750
Purchase and other obligations	14,964	9,814	5,150	—	—
Total	$43,494	$13,957	$25,860	$1,907	$1,770

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

As of December 31, 2012, approximately $0.4 million of contingent contractual payments reflected in accrued expenses and in purchase and other obligations in the table above.

Our purchase and other obligations are primarily associated with our clinical trials, including approximately $10.4 million for our Phase 2 trial evaluating TSO as a treatment for Crohn's disease, including $0.8 million of product supply from Ovamed and approximately $4.4 million for services associated with our planned Phase 1/2 CNDO-109 trial.

In July 2012, the Company entered into a five-year lease for approximately 3,200 square feet of office space in Burlington, Massachusetts at an average annual rent of approximately $94,000. The Company took occupancy of this space in October 2012.

In December 2012, the Company assumed a lease from TSO Laboratories, Inc. a wholly owned subsidiary of Quamed for approximately 8,700 square feet of space in Woburn, Massachusetts. Annual average rent will approximate $118,000 and the Company expects to occupy the space in the second half of 2013.

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, 2011 and 2012. The Company's Loan and Security with Hercules Technology Growth Capital, Inc., or the Hercules Note, pursuant to which the Company issued a $15 million note, 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%. To the extent the prevailing prime rate exceeds 3.25%, the Company will pay a higher rate of interest on any then-outstanding principal balance.

Net Operating Loss Tax Carry-Forwards

As of December 31, 2012, we had net federal operating loss carryforwards of approximately $53.5 million to offset future federal income taxes which expire beginning in 2026 and state operating loss carryforwards of $16.8 million to offset future state taxes which expire beginning in 2030. 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, 2011 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.

Recently Issued Accounting Pronouncements

Refer to 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.

Not applicable.

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 Annual Report.

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, 2012, 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, 2012. 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*.

Based on our assessment, our management has concluded that, as of December 31, 2012, 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, 2012 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.

As of December 28, 2012, Harlan Weisman was hired as the Chairman of the Board of Directors and Chief Executive Officer.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth certain information about our executive officers, key employees and directors as of the date of this Form 10-K. Directors serve until the next annual meeting or their successors have been elected and qualified.

Name	Age	Position
Harlan W. Weisman, M.D.	61	Chairman of the Board of Directors and Chief Executive Officer
Bobby W. Sandage, Jr., Ph.D.	59	President and Director
Noah D. Beerman	51	Executive Vice President and Chief Operating Officer
Lucy Lu, M.D.	38	Executive Vice President and Chief Financial Officer
Karin M. Hehenberger, M.D., Ph.D.	40	Executive Vice President and Chief Medical Officer
Dale Ritter	62	Senior Vice President, Finance and Chief Accounting Officer
Eric K. Rowinsky, M.D.	56	Director, Vice Chairman
David J. Barrett	37	Director
Jimmie Harvey, Jr., M.D.	61	Director
J. Jay Lobell	50	Director
Michael W. Rogers	53	Director
Lindsay A. Rosenwald, M.D.	58	Director

The following is a brief account of the business experience during the past five years (and, in some instances, for prior years) of each director and executive officer of our company.

Executive Officers

Harlan F. Weisman, M.D. has served as a director since August 2012 and our chairman and chief executive officer since December 2012. Dr. Weisman is the founder and Managing Director of And-One Consulting, LLC, a consulting firm which was formed in March 2012 and focuses on assisting companies to formulate and lead successful global strategies for accelerating medical product development, regulatory approval and market acceptance. From October 2005 to March 2012, Dr. Weisman was chief science and technology officer of Johnson & Johnson's Medical Device and Diagnostics business. Dr. Weisman is a graduate of the University of Maryland and the University of Maryland School of Medicine. Dr. Weisman served his residency at Mount Sinai Hospital in New York and was a fellow in cardiovascular disease at Johns Hopkins Hospital. Based on Dr. Weisman's medical background, our board of directors believes that Dr. Weisman has the appropriate set of skills to serve as a member of the board of directors in light of our business and structure.

Bobby W. Sandage, Jr., Ph.D. has served as our president and chief executive officer from April 2011 to December 2012 and since December 2012 has served as our president. Dr. Sandage has over 30 years of experience in the pharmaceutical industry, most recently as the vice president and head of oncology research and development for Covidien Pharmaceuticals, a specialty pharmaceuticals company, a position he held from March 2010 until March 2011. From November 1991 to December 2009, Dr. Sandage held various positions at Indevus Pharmaceuticals, Inc., a specialty pharmaceuticals company, including executive vice president of research and development and chief scientific officer, prior to the sale of the company to Endo Pharmaceuticals. From December 2009 to March 2010, Dr. Sandage was transitioning from his position at Endo Pharmaceuticals to his position at Covidien Pharmaceuticals. Prior to joining Indevus Pharmaceuticals, from 1981 to 1991, Dr. Sandage held senior drug development positions at DuPont Merck Pharmaceutical Company, DuPont Critical Care (formerly American Critical Care) and Merrell Dow Pharmaceuticals. Dr. Sandage is currently a member of the board of directors of Gentium S.p.A., a pharmaceutical company. Dr. Sandage has also served as a member of the board of directors of Osteologix, Inc. and Genta Incorporated. Dr. Sandage has a B.S. in pharmacy from the University of Arkansas and a Ph.D. in clinical pharmacy from Purdue University. Based on Dr. Sandage's

position as the president and chief executive officer, his substantial experience in the pharmaceutical industry and service on boards of directors in the biotechnology and pharmaceutical industries, our board of directors believes that Dr. Sandage has the appropriate set of skills to serve as a member of the board in light of our business and structure.

Noah D. Beerman has served as our executive vice president and chief operating officer since September 26, 2011. Mr. Beerman has over 25 years of experience in the biopharmaceutical industry. Mr. Beerman, who was a consultant to our company from May to September 2011, served as president and chief executive officer and a director of Galena Biopharma, Inc., formerly RXi Pharmaceuticals Corporation, from November 2009 until April 2011. Prior to April 2011, he spent more than 10 years at Indevus Pharmaceuticals, Inc., serving most recently as executive vice president and chief business officer from September 2004 until the sale of the company to Endo Pharmaceuticals, Inc. in 2009. Mr. Beerman received an M.B.A. from Northeastern University's High Technology Program and a B.S. in molecular genetics from the University of Rochester.

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.

Karin M. Hehenberger. M.D., Ph.D. joined us as senior vice president of scientific affairs in December 2011 and has served as our executive vice president and chief medical officer since April 19, 2012. Dr. Hehenberger has over 15 years of experience in the healthcare industry. From January 2010 until joining our company, Dr. Hehenberger was Senior Vice President for Strategic Alliances at the Juvenile Diabetes Research Foundation, or JDRF, where she was responsible for advancing JDRF's involvement with scientific, financial, and commercial partners in the diabetes community. From February 2008 until January 2010, she served as Vice President of Metabolic Strategy and Business Development at Johnson & Johnson. From October 2005 through February 2008, Dr. Hehenberger served as Senior Investment Director and Partner at Scandinavian Life Science Venture. Dr. Hehenberger holds M.D. and Ph.D. degrees from the Karolinska Institute in Stockholm, Sweden and continued her research as a JDRF post-doctoral fellow at the Joslin Diabetes Center at Harvard Medical School.

Dale Ritter has served as our senior vice president, finance, and chief accounting officer since May 2011. Mr. Ritter also served as acting chief financial officer until February 2012. Mr. Ritter has over 20 years of experience in the pharmaceutical industry. From September 2009 until joining us in May 2011, he was an independent consultant, serving as a financial consultant to Helicos BioSciences Corporation, an innovative genetic analysis technologies company. From 1994 to 2009, Mr. Ritter was the senior vice president of finance and chief accounting officer at Indevus Pharmaceuticals until the sale of the company to Endo Pharmaceuticals. Mr. Ritter has a B.A. from Syracuse University and an M.B.A. from Babson College Graduate School of Business Administration.

Non-Employee Directors

Eric K. Rowinsky, M.D. has served as a member of our board of directors, as our vice chairman and a consultant since October 2010 and is responsible for overseeing our clinical development plan for acute myeloid leukemia and solid tumor malignancies. Dr. Rowinsky is an internationally renowned expert in oncology with a distinguished background in academics and industry. Following an oncology fellowship at Johns Hopkins, he became an assistant professor of oncology at Johns Hopkins and then an associate professor at Johns Hopkins. Dr. Rowinsky then became a professor of medicine and director for drug development, cancer therapy and research at University of Texas, San Antonio. In 2004, Dr. Rowinsky became chief medical officer and senior vice president (later promoted to executive vice president) of ImClone Systems, Inc., a cancer therapeutics company, and spear-headed the further clinical development of Erbitux (cetuximab injection) and eight

additional monoclonal antibodies, prior to ImClone's acquisition by Eli Lilly & Company in 2008. He remained at ImClone as a consultant until December 2010. Dr. Rowinsky is and has been a consultant to multiple biotech companies in cancer drug development and serves on the boards of directors of Biogen-Idec Inc., Neoprobe Inc., PreScience Labs Inc., and DLVR, Inc., each of which are life sciences companies. During the past five years, Dr. Rowinsky has also served on the boards of directors of Tapestry Pharmaceuticals, Inc. and Adventrx Pharmaceuticals, Inc., which are life sciences companies. Dr. Rowinsky has been an advisor to academic, industrial and FDA advisory boards and has more than 300 peer-reviewed publications. Dr. Rowinsky received his B.A. from New York University and his M.D. from Vanderbilt University School of Medicine. Based on Dr. Rowinsky's service on boards of directors in the biotechnology and pharmaceutical industries and his extensive experience and background in oncology, our board of directors believes that Dr. Rowinsky has the appropriate set of skills to serve as a member of the board in light of our business and structure.

David J. Barrett has served as a member of our board of directors since May 2011. In July 2010, after transitioning from Neuro-Hitech, Inc., Mr. Barrett became the chief financial officer of Ventrus Biosciences, Inc., a pharmaceutical company focused on the late-stage clinical development of gastrointestinal products. From April 2006 to September 2009, Mr. Barrett served as chief financial officer of Neuro-Hitech, Inc., a publicly traded company focused on developing, marketing and distributing branded and generic pharmaceutical products. From September 2003 to April 2006, Mr. Barrett was the chief financial officer/vice president of finance of Overture Asset Managers and Overture Financial Services, which, at the time, was a start-up asset management firm that assembled investment products and platforms to distribute turnkey and unbundled investment solutions to financial intermediaries and institutional investors. From July 1999 to September 2003, Mr. Barrett was employed as a manager at Deloitte & Touche, LLP. Mr. Barrett received his B.S. in accounting and economics in May 1998 and his M.S. in accounting in May 1999 from the University of Florida. He is a certified public accountant. Based on Mr. Barrett's management experience, particularly in areas of finance and investment management, our board of directors believes that Mr. Barrett has the appropriate set of skills to serve as a member of the board in light of our business and structure.

Jimmie Harvey, Jr., M.D. has served as a member of our board of directors since December 2008. Dr. Harvey in 1984 founded Birmingham Hematology and Oncology Associates L.L.C., a private medical company located in Birmingham, Alabama. Dr. Harvey has experience in clinical trial execution and management and has recently been a principal investigator in two trials, one investigating a novel monoclonal antibody and the other a small molecule used to treat immunologic malignancies. Dr. Harvey holds a B.A. degree in Chemistry from Emory University and received his M.D. from Emory University School of Medicine. Dr. Harvey completed his medical oncology training at the Vincent T. Lombardi Cancer Center at Georgetown University. Based on Dr. Harvey's medical background, including his oncology expertise, our board of directors believes that Dr. Harvey has the appropriate set of skills to serve as a member of the board in light of our business and structure.

J. Jay Lobell has served as a member of our board of directors since June 2006. Mr. Lobell is president of Meridian Capital Group, LLC, a commercial real estate mortgage company, which he joined as a senior officer in January 2010. Mr. Lobell also is a founder of, and since December 2009 has served as vice chairman of, Beech Street Capital, LLC, a real estate lending company. Since January 2005, Mr. Lobell has served as president and chief operating officer of Paramount Biosciences, LLC, or PBS, a biotechnology investment and development company. In that capacity, he had substantial responsibility for the assembly and oversight of companies founded and incubated by PBS, including Coronado and Asphelia. Mr. Lobell previously has served on the board of directors of NovaDel Pharma Inc., Innovive Pharmaceuticals, Inc. and ChemRx Corporation. Mr. Lobell was a partner in the law firm Covington & Burling LLP from October 1996 through January 2005, where he advised companies and individuals as a member of the firm's securities litigation and white collar defense practice group. Mr. Lobell received his B.A. (summa cum laude, Phi Beta Kappa) from the City University of New York and his J.D. from Yale Law School, where he was senior editor of the Yale Law Journal. Based on Mr. Lobell's biotechnology, legal and financial experience, as well as his in-depth understanding of drug commercialization and corporate governance, our board of directors believes that Mr. Lobell has the appropriate set of skills to serve as a member of the board in light of our business and structure.

Michael W. Rogers has served as a member of our board of directors since May 2011. From June 2009 to October 2012, Mr. Rogers served as the executive vice president, chief financial officer and treasurer of BG Medicine, Inc., a life sciences company focused on the discovery, development, and commercialization of novel diagnostic tests. Prior to joining BG Medicine, Inc. and since 1999, Mr. Rogers held the position of executive vice president, chief financial officer and treasurer at Indevus Pharmaceuticals, Inc., a specialty pharmaceuticals company, which was acquired by Endo Pharmaceuticals in 2009. In 1998, Mr. Rogers was executive vice president and chief financial and corporate development officer at Advanced Health Corporation, a publicly traded healthcare information technology company. From 1995 to 1997, he was vice president, chief financial officer and treasurer of AutoImmune, Inc., a publicly-traded biopharmaceutical company. From 1994 to 1995, Mr. Rogers was vice president, investment banking at Lehman Brothers, Inc. From 1990 to 1994, he was associated with PaineWebber, Inc., serving most recently as vice president, investment banking division. Mr. Rogers serves as a director of pSivida, Inc., a publicly-traded medical device company. Mr. Rogers received an M.B.A. from the Darden School at the University of Virginia and a B.A. from Union College. Based on Mr. Rogers's management experience, particularly in areas of finance and corporate development, our board of directors believes that Mr. Rogers has the appropriate set of skills to serve as a member of the board.

Lindsay A. Rosenwald, M.D. has served as a member of our board of directors since October 2009. Since November 2008, Dr. Rosenwald has served as Co-Portfolio Manager & Partner of Opus Point Partners, LLC, or Opus, an asset management and broker dealer in the life sciences industry. Prior to that, from August 1991 to October 2008, he served as the Chairman of Paramount BioCapital, Inc., or PBC. 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. Based on Dr. Rosenwald's biotechnology and pharmaceutical industry experience and in-depth understanding of our business, our board of directors believes that Dr. Rosenwald has the appropriate set of skills to serve as a member of the board in light of our business and structure.

Director Independence

Board Leadership Structure

Our board of directors has a chairman, currently Dr. Weisman, who has authority, among other things, to call and preside over board meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the chairman has substantial ability to shape the work of the board of directors. The board of directors believes that having our CEO serve as chairman of the board of directors is suitable for our company at its present stage. Dr. Weisman possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing our company and its business, and is well positioned to develop agendas that ensure the board of director's time and attention are focused on the most critical matters. Furthermore, the board believes that having our chief executive officer serve as chairman of the board of directors strengthens his ability to develop and implement strategic initiatives and respond efficiently to various situations. The board of directors is aware of potential conflicts that might arise when an employee chairs the board of directors, but believes these potential conflicts are offset by the fact that independent directors comprise each of the committees of the board of directors and a majority of the board of directors. Additionally, the board of directors believes Dr. Weisman's combined role enables decisive leadership and ensures clear accountability. Until December 28, 2012, Dr. Sandage was our chief executive officer and president and, since that time, he remains our president.

There is no lead independent director for our board of directors, but we believe that our current leadership structure is appropriate, as the majority of our board of directors is composed of independent directors and each committee of our board of directors is chaired by an independent director. The board of directors considers all of its members equally responsible and accountable for oversight and guidance of its activities.

Role of the Board in Risk Oversight

The board of directors is responsible for our company's risk oversight and has delegated that role to the audit committee. Our audit committee is primarily responsible for overseeing our risk management processes on behalf of the full board of directors. The audit committee receives reports from management at least quarterly regarding our assessment of risks. In addition, the audit committee reports regularly to the full board of directors, which also considers our risk profile. The audit committee and the full board of directors focus on the most significant risks we face and our general risk-management strategies. While the board oversees our risk management, management is responsible for day-to-day risk management processes. Our board of directors expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk-management strategies and processes for day-to-day activities and to effectively implement risk-management strategies adopted by the audit committee and the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board leadership structure, which also emphasizes the independence of the board in its oversight of its business and affairs, supports this approach.

Board Committees

The audit committee comprises Messrs. Rogers, Barrett and Lobell, each of whom is an independent director as defined in Rule 5605(a)(2) of the NASDAQ Marketplace Rules and Section 10A(m)(3) of the Exchange Act. Mr. Rogers serves as the chair of the audit committee.

The functions of the audit committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non- audit services;
- reviewing our annual and quarterly financial statements and reports and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation, and matters concerning the scope, adequacy and effectiveness of our financial controls;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
    - preparing the report that the SEC will require in our annual proxy statement;
- reviewing and providing oversight with respect to any related party transactions and monitoring compliance with a code of ethics that we will adopt;
    - reviewing our investment policy on a periodic basis; and
- reviewing and evaluating, at least annually, the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that each member of the audit committee meets the financial literacy requirements under the applicable NASDAQ Marketplace Rules and that Mr. Rogers' employment experience qualifies him as an audit committee financial expert within the meaning of SEC rules and regulations.

The compensation committee comprises Mr. Rogers and Drs. Harvey and Rosenwald. Mr. Rogers serves as the chair of the compensation committee. The functions of the compensation committee include, among other things:

- reviewing our corporate goals and objectives relevant to our executives' compensation, evaluating the executives' performance in light of such goals and objectives and determining, either as a committee or together with the other independent directors, executive compensation levels based on such evaluations;
- reviewing and making recommendations to the Board with respect to non-executive officer compensation and independent director compensation;
    - administering our incentive compensation and equity-based plans;
    - preparing the report that the SEC will require in our annual proxy statement and Form 10-K; and
- reviewing and evaluating, at least annually, the performance of the compensation committee, and the adequacy of its charter.

The nominating and corporate governance committee of the board originally comprised Mr. Lobell and Dr. Rosenwald. Mr. Lobell serves as the chair of the nominating and corporate governance committee. The functions of the nominating and corporate governance committee include, among other things:

    - making recommendations to the Board regarding the size and composition of the Board;
    - establishing procedures for the nomination process and screening and recommending candidates for election to the Board;
- establishing and administering a periodic assessment procedure relating to the performance of the Board as a whole and its individual members; and
- making recommendations to the Board regarding corporate governance matters and practices, including formulating and periodically reviewing corporate governance guidelines to be adopted by the Board.

Each of the above-referenced committees operates pursuant to a formal written charter. The charters for each committee, which have been adopted by the Board, contain a detailed description of the respective committee's duties and responsibilities and are available under *Committee Charting* in the *Investors – Governance* section of our website at **www.coronadobiosciences.com**.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own more than 10% of a registered class of our equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. These executive officers, directors, and greater than 10% beneficial owners are required by SEC regulation to furnish us with copies of all Section 16(a) forms filed by such reporting persons.

Based solely on our review of such forms furnished to us, we believe that during the prior fiscal year, all of our executive officers and directors and every person who is directly or indirectly the beneficial owner of more than 10% of any class of our security complied with the filing requirements of Section 16(a) of the Exchange Act.

Code of Ethics

We adopted a Code of Ethics that applies to all directors, officers and employees. Our Code of Ethics is available on our website at **www.coronadobiosciences.com**. A copy of our code of ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 24 New England Executive Park, Burlington, Massachusetts 01803.

Material Changes to the Procedures by which Security Holders May Recommend Nominees to the Board of Directors

There have been no material changes to the procedures by which security holders may recommend nominees to the board of directors.

Item 11. Executive Compensation.

Compensation Committee Interlocks and Insider Participation

The members of the board of directors who served on the compensation committee in 2012 are Jimmie Harvey, Jr., M.D., Michael W. Rogers and Lindsay A. Rosenwald, M.D. None of these individuals has ever served as an officer or employee of ours. None of the members of the compensation committee serves or in the past has served as one of our officers or has been employed by us and none of our executive officers have served on the compensation committee or board of any company that employed any member of our compensation committee or board of directors.

In June 2012, we issued an aggregate of 5,750,000 shares of common stock in an underwritten offering, or the June 21012 Offering, for an aggregate purchase price of $28.8 million. Dr. Rosenwald, who serves on our compensation committee and is also a principal stockholder, purchased an aggregate of 200,000 shares of our common stock in the June 2012 Offering. For additional discussion regarding the June 2012 Offering, please see Item 13 “Certain Relationships and Related Transactions, and Director Independence” below.

Compensation Committee Report

The compensation committee has reviewed and discussed the following Compensation Discussion and Analysis (“CD&A”) with our Company’s management. Based on this review and discussion, the compensation committee recommended to the board of directors that the CD&A be included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS

Michael W. Rogers, chair

Jimmie Harvey, Jr., M.D.

Lindsay A. Rosenwald, M.D.

Compensation Discussion and Analysis

Introduction

This Compensation Discussion and Analysis explains our compensation philosophy, policies and practices with respect to our named executive officers. The compensation committee of the board is responsible for creating and reviewing the compensation of our executive officers, as well as overseeing our compensation and benefit plans and policies and administering our equity incentive plans.

Compensation Philosophy

We believe in providing a competitive total compensation package to our executive management team through a combination of base salary, discretionary bonuses, grants under an equity incentive compensation plan, severance and change in control benefits and broad-based benefits programs. Our executive compensation programs are designed to achieve the following objectives:

- attract, motivate and retain executives of outstanding ability and potential;
- reward achievement; and
- ensure that executive compensation is meaningfully related to the creation of stockholder value.

Our board of directors believes that our executive compensation programs should include short- and long-term components, including cash and equity-based compensation, and should reward consistent performance that

meets or exceeds expectations. The board evaluates both performance and compensation to make sure that the compensation provided to executives remains competitive relative to compensation paid by companies of similar size and stage of development operating in the life sciences industry, taking into account our relative performance and our own strategic objectives.

Setting Executive Compensation

We have historically conducted a review of the aggregate level of our executive compensation, as well as the mix of elements used to compensate our executive officers. We have based this review primarily on the experience of the members of our board of directors, many of whom sit on the boards of directors of numerous companies in the life sciences and healthcare fields. It is expected that in the future, our compensation committee will take into account publicly available data relating to the compensation practices and policies of other companies within and outside our industry. Although we expect the compensation committee to use such survey data as a tool in determining executive compensation, we expect that members of the compensation committee will continue to apply their subjective discretion to make compensation decisions. Our board has not yet determined to benchmark executive compensation against any particular group of companies or use a formula to set executive compensation in relation to such survey data.

Elements of Executive Compensation

The compensation program for our executive officers consists principally of three components:

- base salary;
- annual discretionary bonuses; and
- long-term compensation in the form of stock options or other equity-based awards.

Base Salary

Base salaries for our executives are initially established through arm's-length negotiation at the time the executive is hired, taking into account such executive's qualifications, experience, prior salary, the scope of his or her responsibilities, and competitive market compensation paid by other companies for similar positions within the industry. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In making decisions regarding salary increases, we may also draw upon the experience of members of our board of directors with other companies. The board of directors has not previously applied specific formulas to determine increases, although it has generally awarded increases as a percentage of an executive officer's then-current base salary. This strategy is consistent with our intent of offering base salaries that are cost-effective while remaining competitive.

We hired our former executive chairman, Dr. Cooper, in July 2010. Initially, Dr. Cooper was compensated as a consultant for a monthly fee of $25,000. This amount was determined as part of the negotiation of Dr. Cooper's compensation, conducted on our behalf by Dr. Rosenwald and our former chief executive officer and approved by the board of directors. In April 2011, Dr. Cooper's consulting arrangement was transitioned into an employment arrangement and his annual base salary of $300,000 was approved by the board of directors at that time. In connection with Dr. Cooper's resignation from the board of directors in December 2012,, we entered into a one-year consulting agreement with Dr. Cooper that provides for monthly payments of $25,000.

We hired Bobby W. Sandage, Jr., Ph.D. to serve as our president and chief executive officer in April 2011. Dr. Sandage's annual base salary for 2011 was set at $375,000. This salary was determined as part of the negotiation of Dr. Sandage's employment agreement, which was conducted by Dr. Cooper on our behalf and approved by the board of directors. In approving the salary, the board considered Dr. Sandage's requested salary and the salaries of other members of the management team. Dr. Sandage's salary was most similar to that of the

preceding chief executive officer, reflective of the fact that Dr. Sandage succeeded such person as our president and chief executive officer. In February 2012, Dr. Sandage's base salary was increased to $395,000 to recognize his performance and achievements in 2011. Dr. Sandage's salary was increased to $406,850 reflecting a 3% cost of living adjustment.

We hired Noah D. Beerman to serve as our executive vice president and chief operating officer in September 2011. Mr. Beerman's base salary for 2011 was set at $325,000. This salary was determined as part of the negotiation of Mr. Beerman's employment agreement, which was conducted by Drs. Cooper and Sandage on our behalf and approved by the board of directors. In approving the salary, the board considered Mr. Beerman's requested salary and the salaries of other members of the management team. In February 2012, Mr. Beerman's base salary was increased to $328,000 and in 2013 it was increased to $337,840 reflecting a 3% cost of living adjustment.

We hired Lucy Lu, M.D. to serve as our executive vice president and chief financial officer in February 2012. Dr. Lu's base salary for 2012 was set at $300,000. This salary was determined as part of the negotiation of Dr. Lu's employment agreement, which was conducted by Dr. Sandage on our behalf and approved by the board of directors. In approving the salary, the board considered Dr. Lu's requested salary and the salaries of other members of the management team. In 2013, Dr. Lu's base salary was increased to $307,875 reflecting a 3% cost of living adjustment.

We hired Karin M. Hehenberger, M.D., Ph.D. to serve as our senior vice president of scientific affairs in December 2011 and appointed Dr. Hehenberger executive vice president and chief medical officer on April 19, 2012. Dr. Hehenberger's base salary for 2012 was set at $300,000. This salary was determined as part of the negotiation of Dr. Hehenberger's employment agreement, which was conducted by Dr. Sandage on our behalf and approved by the board of directors. In approving the salary, the board considered Dr. Hehenberger's requested salary and the salaries of other members of the management team. In 2013, Dr. Hehenberger's base salary was increased to $309,000 reflecting a 3% cost of living adjustment.

We hired Dale Ritter to serve as our senior vice president, finance, chief accounting officer and acting chief financial officer in May 2011. Mr. Ritter's base salary for 2011 was set at $250,000. This salary was determined as part of the negotiation of Mr. Ritter's employment agreement, which was conducted by Drs. Cooper and Sandage on our behalf and approved by the board of directors. In approving the salary, the board considered Mr. Ritter's requested salary and the salaries of other members of the management team. Mr. Ritter's salary was most similar to that of the preceding chief financial officer, reflective of the fact that Mr. Ritter succeeded to much of the preceding chief financial officer's responsibilities, while taking in account the fact this his role as acting chief financial officer was temporary until such time as we retained Dr. Lu as our full-time chief financial officer. In February 2012, Mr. Ritter's base salary was increased by the board of directors to $275,000 as an incentive to retain Mr. Ritter's services subsequent to the hiring of Dr. Lu and in 2013 it was increased to $283,250 reflecting a 3% cost of living adjustment.

We hired Harlan W. Weisman, M.D. to serve as our chairman and chief executive officer in December 2012 and entered into an employment agreement with Dr. Weisman on January 7, 2013. Dr. Weisman's annual base salary for 2013 was set at $600,000. This salary was determined as part of the negotiation of Dr. Weisman's employment agreement, which was conducted by Dr. Rosenwald on our behalf and approved by the board of directors. In approving the salary, the board considered Dr. Weisman's requested salary and the salaries of other members of the management team.

Annual Discretionary Bonuses

In addition to the payment of base salaries, we believe that discretionary bonuses can play an important role in providing appropriate incentives to our executives to achieve our strategic objectives. As part of the annual performance reviews, the compensation committee reviews and analyzes each executive officer's overall performance against such executive's goals as approved by the compensation committee. Dr. Sandage,

Mr. Beerman, Dr. Lu, Dr. Hehenberger and Mr. Ritter are eligible for a maximum discretionary bonus of 50%, 45%, 40%, 40% and 40%, respectively, of their respective salaries pursuant to the terms of their employment agreements. In addition, Dr. Sandage is eligible for additional bonuses of $137,500, $125,000, $250,000, and $500,000 based on the achievement of milestones tied to reaching a market capitalization of $125 million, $250 million, $500 million and $1 billion, respectively. Mr. Beerman and Dr. Lu are also eligible for additional discretionary bonuses of $46,875, $93,750, $187,500, and $375,000 based on the achievement of milestones tied to reaching a market capitalization of $125 million, $250 million, $500 million and $1 billion, respectively. In 2013, the first additional bonuses were earned and paid as follows: $137,500 to Dr. Sandage and $46,875 to each of Mr. Beerman and Dr. Lu.

Following the end of 2011, our board of directors reviewed the annual performances in 2011 of Dr. Sandage, Mr. Beerman and Mr. Ritter, the only executive officers eligible for a discretionary bonus, as well as our overall performance and approved the payments of discretionary bonuses to Dr. Sandage in the amount of $140,000, Mr. Beerman in the amount of $39,000 and Mr. Ritter in the amount of $62,000. Such discretionary bonuses were paid in cash in 2012 and were provided in order to continue to motivate the executives to achieve our financial and business objectives and was paid in part based on achievements made by the executives and by us during 2011.

Following the end of 2012, our compensation committee of board of directors reviewed the annual performances in 2012 of Dr. Sandage, Mr. Beerman, Dr. Lu, Dr. Hehenberger and Mr. Ritter, the only executive officers eligible for a discretionary bonus. The compensation committee reviewed the 2012 performance targets which included goals related to initiating and conducting clinical trials, business development, transactions, and maintenance of cash balances, the weight given to each target, specific comments and circumstances surrounding each target and the Company's overall performance. After detailed discussion, the compensation committee approved that 2012 executive bonuses be paid at 90% of the full bonus amount and approved bonuses, prorated for the time each person was employed by Coronado, to Mr. Beerman in the amount of $132,840, Dr. Lu in the amount of $92,492, Dr. Hehenberger in the amount of $108,000 and Mr. Ritter in the amount of $99,000. Dr. Sandage received a bonus of $200,000 pursuant to his amended employment agreement.

Dr. Weisman is eligible for an annual bonus. At the beginning of each calendar year, but no later than February 15 of such calendar year, or later as agreed between Dr. Weisman and the compensation committee in writing, Dr. Weisman and the compensation committee shall meet and establish the parameters of Dr. Weisman's annual bonus. The parameters of his annual bonus shall establish a target and range of bonus amounts as a percent of his base salary. The amount of bonus to be paid shall be based on Dr. Weisman's attainment of certain financial, clinical development, and/or business milestones, or the Weisman Milestones, to be established and agreed to annually by the compensation committee and Dr. Weisman. The Weisman Milestones shall be defined business objectives, and whether or not any such objectives have been met shall not be subject to the Company's discretion.

On December 28, 2012, in connection with the amendment of Dr. Sandage's employment agreement, the board of directors approved the payment to Dr. Sandage of his 2012 performance bonus of $200,000 as well as a retention bonus of $100,000 payable on December 31, 2013, if he remains employed through that date.

Long-Term Incentive Plan.

We believe that by providing our executives the opportunity to increase their ownership of our stock, the interests of our executives will be more closely aligned with the best interests of our stockholders and we will encourage long-term performance. The stock awards enable our executive officers to participate in the appreciation of the value of our stock, while personally participating in the risks of business setbacks. We have not adopted stock ownership guidelines and our stock incentive plan has provided our executive officers a means to acquire equity or equity-linked interests in our company. We do not have any program, plan or obligation that requires us to grant equity compensation on specified dates. Authority to make equity grants to executive officers rests with our

board of directors, which considers the recommendations of the executive chairman and the chief executive officer for officers other than themselves, and will in the future take into account the recommendation of the compensation committee.

We have granted equity awards primarily through our 2007 Stock Incentive Plan, or the 2007 Plan, which was adopted by our board of directors and stockholders to permit the grant of stock options, stock bonuses and restricted stock to our officers, directors, employees and consultants. The material terms of our 2007 Plan are further described under "2007 Stock Incentive Plan" below.

Dr. Sandage was awarded an option in April 2011 to purchase 300,000 shares of our common stock under the 2007 Plan in connection with the commencement of his employment. The number of shares was determined as part of the negotiation of his overall employment package and was approved by our board of directors. In approving the number of shares, the board considered the number of shares requested by Dr. Sandage and the equity ownership of other members of our management team.

Mr. Beerman was awarded an option to purchase 225,000 shares of our common stock under the 2007 Plan in connection with the commencement of his employment in September 2011. The number of shares was determined as part of the negotiation of his overall employment package and was approved by our board of directors. In approving the number of shares, the board considered the number of shares requested by Mr. Beerman and the equity ownership of other members of our management team.

Dr. Lu was awarded an option to purchase 225,000 shares of our common stock under the 2007 Plan in connection with the commencement of her employment in February 2012. The number of shares was determined as part of the negotiation of her overall employment package and was approved by our board of directors. In approving the number of shares, the board considered the number of shares requested by Dr. Lu and the equity ownership of other members of our management team.

Dr. Hehenberger was awarded an option to purchase 100,000 shares of our common stock under the 2007 Plan in connection with the commencement of her employment in December 2011 and was awarded an option to purchase 125,000 shares of our common stock under the 2007 Plan in connection with her appointment as executive vice president and chief medical officer on April 19, 2012. The number of shares was determined as part of the negotiation of her overall employment packages and was approved by our board of directors. In approving the number of shares, the board considered the number of shares requested by Dr. Hehenberger and the equity ownership of other members of our management team.

Mr. Ritter was awarded an option to purchase 120,000 shares of our common stock under the 2007 Plan in connection with the commencement of his employment in May 2011. The number of shares was determined as part of the negotiation of his overall employment package and was approved by our board of directors. In approving the number of shares, the board considered the number of shares requested by Mr. Ritter and the equity ownership of other members of our management team. In February 2012, Mr. Ritter was awarded an option to purchase an additional 30,000 shares of our common stock under the 2007 Plan.

In connection with his resignation as our executive chairman and his execution of a one-year consulting agreement with us, Dr. Cooper was awarded an option to purchase 25,000 shares of our common stock that will vest on December 28, 2013 if he remains a consultant through that date. The exercise price of the option is $4.75 per share.

Dr. Weisman was awarded an option in January 2013 to purchase 1,686,590 shares of our common stock under the 2007 Plan in connection with his employment agreement. The number of shares was determined as part of the negotiation of his overall employment package and was approved by our board of directors. In approving the number of shares, the board considered the number of shares requested by Dr. Weisman and the equity ownership of other members of our management team.

Prior to November 2011, there was no public trading market for our common stock. In the absence of a public trading market for our common stock at the time any of the grants described above were made, the board of directors determined the fair market value of our common stock in good faith based upon consideration of a number of relevant factors including the status of development efforts, financial status and market conditions and valuations obtained from an independent valuation firm. All options granted after November 2011 were granted at the fair market value of our common stock as determined by the closing price of our shares on NASDAQ on the date of grant.

All option grants typically vest over three years, with one-third of the shares subject to the stock option vesting on each anniversary of the vesting commencement date. All options have a 10-year term. Additional information regarding accelerated vesting upon or following a change in control is discussed below under "Potential Payments Upon Termination or Change in Control."

Executive Employment Agreements

We entered into employment agreements with Dr. Sandage in April 2011, with Mr. Ritter in May 2011, with Mr. Beerman in September 2011, with Dr. Lu in February 2012, with Dr. Hehenberger in April 2012 and with Dr. Weisman in January 2013. All employment agreements provide for at-will employment, base salary, incentive bonuses, standard employee benefit plan participation and recommendations for initial stock option grants. The employment agreements were each subject to execution of standard proprietary information and assignment of invention agreements and proof of identity and work eligibility in the United States.

Dr. Sandage, Mr. Beerman, Dr. Lu, Dr. Hehenberger, Mr. Ritter and Dr. Weisman are each entitled to severance and change in control benefits pursuant to their employment agreements, the terms of which are described below under "Potential Payments Upon Termination or Change in Control" below. We believe that these severance and change in control benefits help us from a retention standpoint and they are particularly necessary in an industry, such as ours, where there has been market consolidation. We believe that they help our executive officers maintain continued focus and dedication to their assigned duties to maximize stockholder value if there is a change in control. We believe that these severance and change in control benefits are an essential element of our overall executive compensation package.

On January 7, 2013, we entered into an employment agreement with Dr. Weisman, our chairman and chief executive officer. Pursuant to the employment agreement, we will pay Dr. Weisman an annual base salary of $600,000. At the discretion of our board of directors, he will also be eligible for an annual cash bonus based on the attainment of financial, clinical development and/or business milestones to be established by our board. Pursuant to the employment agreement, we also granted Dr. Weisman an option to purchase 1,686,590 shares of our common stock, which is equal to 6% of our fully diluted capitalization. The option has an exercise price of $5.57 per share. One-third of the shares underlying the option will vest on December 28, 2013 and each anniversary thereafter, subject to Dr. Weisman's continued employment with our company. Dr. Weisman will be entitled to four weeks paid vacation.

Perquisites

From time to time our board of directors has provided certain of our named executive officers with perquisites that the board believes are reasonable. We do not view perquisites as a significant element of comprehensive compensation structure, but do believe they can be useful in attracting, motivating and retaining the executive talent for which we compete. We believe that these additional benefits may assist our executive officers in performing their duties and provide time efficiencies for executive officers in appropriate circumstances, and we may consider providing additional perquisites in the future. All future practices regarding perquisites will be approved and subject to periodic review by the compensation committee.

Other Compensation

Consistent with our compensation philosophy, we intend to continue to maintain the current benefits for executive officers which are also available to our other employees; however, the compensation committee, in its discretion, may in the future revise, amend or add to the benefits of any executive officer if it deems it advisable.

Deductibility of Compensation under Section 162(m)

Section 162(m) of the Code generally limits our deduction for federal income tax purposes to $1 million of compensation paid to certain executive officers in a calendar year. However, compensation above $1 million that is considered "performance-based compensation" may be deducted. However, it is expected that the compensation committee will evaluate the effects of the deduction limits of Section 162(m) on any compensation it proposes to grant in the future and that future compensation will be provided in a manner consistent with our best interests and those of our stockholders.

Risk Analysis of our Compensation Program

Our board of directors has reviewed our compensation policies as generally applicable to our employees and believes that the policies do not encourage excessive and unnecessary risk taking, and that the level of risk that they do encourage is not reasonably likely to have a material adverse effect on us. The design of our compensation policies and programs encourage the employees to remain focused on both short- and long-term goals. For example, while our cash bonus plans measure performance on an annual basis, the equity awards typically vest over a number of years, which we believe encourages employees to focus on sustained stock price appreciation, thus limiting the potential value of excessive risk- taking.

Summary Compensation Table

The following table provides information regarding the compensation paid during the years ended December 31, 2011 and 2012 to our principal executive officer and certain of our other executive officers, who are collectively referred to as "named executive officers" elsewhere in this Form 10-K. Since none of our named executive officers served us during the year ended December 31, 2010, we have no information to disclose regarding compensation paid during that year.

Name and Principal Position	Year	Salary	Bonus[3]	Option Awards[1]	All Other Compensation[2]	Total
Harlan W. Weisman, M.D.	2012	$ 4,615	$ —	$ 120,250	$ 13,125	$ 137,990
Chairman and Chief Executive Officer	2011	—	—	—	—	—
	2010	—	—	—	—	—
Bobby W. Sandage, Jr. Ph.D.	2012	395,000	200,000	—	3,926	598,926
President and Former Chief Executive	2011	284,135	140,000	257,280	133,929	795,344
Officer	2010	—	—	—	—	—
Noah D. Beerman	2012	328,000	132,840	—	3,820	464,660
Executive Vice President and Chief	2011	87,500	36,000	484,425	—	607,925
Operating Officer	2010	—	—	—	—	—
Lucy Lu, M.D.	2012	256,923	92,492	1,523,250	683	1,873,348
Executive Vice President and Chief	2011	—	—	—	—	—
Financial Officer	2010	—	—	—	—	—
Karin M. Hehenberger, M.D., Ph.D.	2012	300,000	108,000	763,750	820	1,172,570
Executive Vice President and Chief	2011	17,115	5,135	481,440	—	503,690
Medical Officer	2010	—	—	—	—	—
Dale Ritter	2012	272,128	99,000	203,100	8,340	582,568
Senior Vice President, Finance and Chief	2011	149,939	62,000	102,912	7,875	322,726
Accounting Officer	2010	—	—	—	—	—

(1) Option awards for Dr. Weisman consists of an option to purchase 25,000 shares of our common stock granted to Dr. Weisman upon his appointment to our board of directors in August 2012. Represents the

aggregate grant date fair value computed in accordance with FASB Accounting Standards Codification Topic 718, Stock Compensation, as modified or supplemented. One-third of the shares subject to each of the options granted to our named executive officers vest on each anniversary of the grant date such that all of the shares subject to the options will be vested three years after such date.

(2) All other compensation for Dr. Weisman reflects fees earned and paid as a non-employee director in 2012; for Dr. Sandage includes: for 2012, $3,926 for reimbursement of life insurance premiums; for 2011, $130,321 related to reimbursement of moving expenses Dr. Sandage owed his prior employer pursuant to his termination of employment and $3,608 for reimbursement of life insurance premiums; for Mr. Beerman: for 2012, $3,000 for reimbursement of life insurance premiums and $820 for long-term disability premiums; for Dr. Lu: for 2012, $683 for long-term disability premiums; for Dr. Hehenberger: for 2012, $820 for long-term disability premiums; for Mr. Ritter: for 2012, $8,340 for reimbursement of life insurance premiums. In addition to the above, we agreed to provide Dr. Weisman mutually agreeable living accommodations in New York, New York at our sole cost. We also agreed to reimburse him for any taxes associated with such residence during his employment with us.

(3) Bonus amounts in 2011 represent amounts awarded for 2011 and paid in 2012. Bonus amounts in 2012 represent amounts awarded for 2012, to be paid in 2013.

Potential Payments Upon Termination or Change in Control

Regardless of the manner in which a named executive officer's employment terminates, the named executive officer is entitled to receive amounts earned during his term of employment, including salary and unused vacation pay. In addition, each of our named executive officers that are currently employed by us is entitled to severance and change in control benefits described below.

Dr. Bobby W. Sandage, Jr.

In April 2011, we entered into an employment agreement with Dr. Sandage, our then-current president and chief executive officer, which provided that if we terminate Dr. Sandage without cause or he resigns for good reason, he will be entitled to: (i) severance payments at a rate equal to his base salary then in effect for a period of one year following his termination date; and (ii) accelerated vesting of one-third of his stock option shares. In addition, if Dr. Sandage is terminated without cause within six months following a change in control, 100% of the shares subject to options and other equity awards granted to him will fully vest as of the date of his execution of a release in connection with such termination.

Cause is defined as:

- his willful failure, disregard or refusal to perform his material duties or obligations under the employment agreement which, to the extent it is curable by Dr. Sandage, is not cured within thirty (30) days after we give written notice to him;
- any willful, intentional or grossly negligent act having the effect of materially injuring (whether financially or otherwise) the business or reputation of us or any of our affiliates;
- willful misconduct by him with respect to any of the material duties or obligations under the employment agreement, including, without limitation, willful insubordination with respect to lawful directions received from the board of directors which, to the extent it is curable by Dr. Sandage, is not cured within thirty (30) days after we give written notice to him;
- indictment of any felony involving moral turpitude (including entry of a *nolo contendere* plea); the determination, after a reasonable and good-faith investigation by us, that he engaged in some form of harassment or discrimination prohibited by law (including, without limitation, age, sex or race harassment or discrimination), unless the actions were specifically directed by the board of directors;
- material misappropriation or embezzlement of the property of us or our affiliates (whether or not a misdemeanor or felony); or

- a material breach of any of the provisions of the employment agreement, of any company policy, and/or of his proprietary information and inventions agreement.

Good reason is defined as:

- a material reduction of Dr. Sandage's base salary unless such reduction occurs in connection with a company-wide decrease in executive compensation;
- a material breach of the employment agreement by us; or
- a material adverse change in his duties, authority, or responsibilities relative to his duties, authority, or responsibilities in effect immediately prior to such reduction.

On December 28, 2012, Dr. Sandage became president of the Company. He remains a member of our board of directors. Dr. Sandage's change in status from chief executive officer and president to president entitles him to terminate his employment agreement for good reason, in which case we 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.

Also effective December 28, 2012, we 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 of $395,000 for 12 months and have any unvested options vest in full. Also, the amended employment agreement provides that in the event Dr. Sandage terminates 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, we will be required to pay his COBRA premiums for 12 months after such termination. Also on December 28, 2012, our board of directors approved the payment to Dr. Sandage of his 2012 performance bonus of $200,000 as well as a retention bonus of $100,000 payable on December 31, 2013, if he remains employed through that date.

Dr. Harlan Weisman

Dr. Weisman's employment agreement is terminable upon his death or disability, in which event we will continue to pay his salary for 90 days following the date of such termination, we will pay him a pro rata share of his annual bonus if such bonus is awarded, and any options that would have vested on the next anniversary date of their respective grant date will automatically vest. If we terminate the employment agreement without cause or Dr. Weisman terminates his employment with good reason, then we will continue to pay Dr. Weisman his then-current salary for 12 months following the date of such termination, we will pay Dr. Weisman a pro rata share of his annual bonus if such bonus is awarded, and any options that would have vested on the next anniversary date of their respective grant date will automatically vest. If termination without cause or for good reasonoccurs on the date of, or within six months of a change in control of our company, then we will continue to pay Dr. Weisman his then-current salary for 12 months following such termination, we will pay Dr. Weisman a pro rata share of his annual bonus if such bonus is awarded, and all unvested options will automatically vest in full. The employment agreement provides that no compensation or benefit that qualifies as a nonqualified deferred compensation plan under Section 409A of the Internal Revenue Code of 1986, as amended, or the Code, will be paid or provided to Dr. Weisman before the earlier of his death or the day that is six months plus one day after the termination date. In addition, if an excess parachute payment is made to Dr. Weisman in the event of a change in control, we will make a gross-up payment to Dr. Weisman to reimburse him for any taxes due pursuant to Section 4999 of the Code with respect to the excess parachute payment as well as for the taxes on such reimbursement. The employment agreement prohibits Dr. Weisman from competing with us in the United States during the term of his employment with us or while he is receiving severance benefits under the employment agreement and for six months thereafter.

Cause is defined as:

- his conviction for fraud, embezzlement or misappropriation with respect to the Company, or his conviction or plea of nolo contendere in respect of a felony or a misdemeanor involving moral turpitude;

- his material breach of a material term of his employment agreement;
- his material breach of his proprietary information and inventions agreement;
- any material breach of his fiduciary duties to our Company;
- willful failure or refusal to perform his material duties under his employment agreement, or failure to follow any specific lawful instructions of our board of directors;
- any willful or negligent misconduct that has a material adverse effect on the property, business or reputation of the Company.

Good Reason is defined as:

- a material reduction of his base salary unless such reduction occurs in connection with a company-wide decrease in executive compensation;
- a material diminution of his authority, duties, or responsibilities;
- the relocation of his office from the New York, New York/New Jersey metro area;
- a material breach of his employment agreement by us; or
- the closing of a transaction resulting in dilution of his percentage ownership of our Company where he has stated his disapproval of such transaction and voted against its authorization in his capacity as a director.

Change in Control is defined as the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

- the acquisition by a third party of securities of our Company representing more than fifty percent (50%) of the combined voting power of our Company's then-outstanding securities other than by virtue of a merger, consolidation or similar transaction;
- a merger, consolidation or similar transaction following which our stockholders immediately prior thereto do not own at least fifty percent (50%) of the combined outstanding voting power of the surviving entity (or that entity's parent) in such merger, consolidation or similar transaction;
- the dissolution or liquidation of our Company; or
- the sale, lease, exclusive license or other disposition of all or substantially all of the assets of our Company.

Mr. Dale Ritter

In May 2011, we entered into an employment agreement with Mr. Ritter, our senior vice president, finance, chief accounting officer and then-acting chief financial officer, which provides that if we terminate Mr. Ritter without cause or he resigns for good reason, he will be entitled to: (i) severance payments at a rate equal to his base salary then in effect for a period of six months following his termination date; and (ii) accelerated vesting of one-third of his stock option shares. In addition, if Mr. Ritter is terminated without cause within six months following a change in control, he will be entitled to an additional six months of severance payments (for a total of 12 months) and 100% of the shares subject to options and other equity awards granted to him will fully vest as of the date of his execution of a release in connection with such termination. Cause and good reason are defined as they are for Dr. Sandage and described above.

Mr. Noah Beerman

In September 2011, we entered into an employment agreement with Mr. Beerman, our executive vice president and chief operating officer, which provides that if we terminate Mr. Beerman without cause or he resigns for good reason, he will be entitled to: (i) severance payments at a rate equal to his base salary then in effect for a period of six months following his termination date; and (ii) accelerated vesting of one-third of his stock option

shares. In addition, if Mr. Beerman is terminated without cause within six months following a change in control, he will be entitled to an additional six months of severance payments (for a total of 12 months) and 100% of the shares subject to options and other equity awards granted to him will fully vest as of the date of his execution of a release in connection with such termination. Cause and good reason are defined as they are for Dr. Sandage and described above.

Dr. Lucy Lu

In February 2012, we entered into an employment agreement with Dr. Lu, our executive vice president and chief financial officer, which provides if we terminate Dr. Lu without cause or she resigns for good reason, she will be entitled to: (i) severance payments at a rate equal to her base salary then in effect for a period of six months following her termination date; and (ii) accelerated vesting of one-third of her stock option shares. In addition, if Dr. Lu is terminated without cause within six months following a change in control, she will be entitled to an additional six months of severance payments (for a total of 12 months) and 100% of the shares subject to options and other equity awards granted to her will fully vest as of the date of her execution of a release in connection with such termination. Cause and good reason are defined as they are for Dr. Sandage and described above.

Dr. Karin Hehenberger

In April 2012, we entered into an employment agreement with Dr. Hehenberger, our executive vice president and chief medical officer, which provides if we terminate Dr. Hehenberger without cause or she resigns for good reason, she will be entitled to:

(i) severance payments at a rate equal to her base salary then in effect for a period of six months following her termination date; and (ii) accelerated vesting of one-third of her stock option shares. In addition, if Dr. Hehenberger is terminated without cause within six months following a change in control, she will be entitled to an additional six months of severance payments (for a total of 12 months) and 100% of the shares subject to options and other equity awards granted to her will fully vest as of the date of her execution of a release in connection with such termination. Cause and good reason are defined as they are for Dr. Sandage and described above.

The following table sets forth potential payments payable to our named executive officers upon: (i) termination of employment without cause, or resignation for good reason; and (ii) termination of employment without cause, or resignation for good reason, following a change in control. The table below reflects amounts payable to our executive officers assuming their employment was terminated on December 31, 2012 and, if applicable, a change in control also occurred on such date.

	Upon Termination without Cause or Resignation for Good reason — No Change of Control			Upon Termination without Cause or Resignation for Good reason — Change of Control		
Name	Cash Severance	Value of Accelerated Vesting (1)	Total	Cash Severance	Value of Accelerated Vesting (1)	Total
Harlan Weisman, M.D. (2)	$ —	$ —	$ —	$ —	$ —	$ —
Bobby W. Sandage, Jr., Ph.D. (3)	395,000	258,000	653,000	395,000	516,000	911,000
Noah D. Beerman (4)	164,000	117,000	281,000	328,000	234,000	562,000
Lucy Lu, M.D. (4)	150,000	—	150,000	300,000	—	300,000
Karin M. Hehenberger, M.D., Ph.D. (4)	150,000	—	150,000	300,000	—	300,000
Dale Ritter (4)	137,500	103,200	240,700	275,000	206,400	481,400

(1) The value of accelerated vesting is equal to $4.51 per share, the closing price per share of our common stock as quoted on NASDAQ on December 31, 2012 for the purposes hereof, multiplied by the number of shares subject to accelerated vesting, less the stock option exercise price.

(2) Dr. Weisman's employment agreement was entered into on January 7, 2013 and he was not eligible for termination benefits as of December 31, 2012.

(3) Dr. Sandage's employment agreement provides that: (a) if he is terminated without cause or resigns for good reason, not in connection with a change in control, he will receive 12 months of salary continuation and accelerated vesting of 1/3rd of the number of options outstanding and (b) if he is terminated without cause or resigns for good reason within six months following a change in control, he will receive 12 months of salary continuation and accelerated vesting of 100% of the number of options outstanding.

(4) Mr. Beerman's, Dr. Lu's, Dr Hehenberger's, and Mr. Ritter's employment agreements provide that: (a) if he or she is terminated without cause or resigns for good reason, not in connection with a change in control, he or she will receive six months of salary continuation and accelerated vesting of 1/3rd of the number of options outstanding and (b) if he or she is terminated without cause or resigns for good reason within six months following a change in control, he or she will receive 12 months of salary continuation and accelerated vesting of 100% of the number of options outstanding.

Grants of Plan-Based Awards

All stock options granted to our named executive officers are incentive stock options to the extent permissible under the Code. The exercise price per share of each stock option granted to our named executive officers was equal to the fair market value of our common stock as determined in good faith by our board of directors taking into consideration independently prepared valuation reports on the date of the grant. All stock options were granted under the 2007 Plan.

The following table sets forth certain information regarding grants of plan-based awards to our named executive officers for 2012.

Name	Grant Date	All other option awards: number of securities underlying options (#)	Exercise or base price of option awards (1)	Grant date fair value of option award (2)
Harlan Weisman, M.D.(3)	8/16/12	25,000	$5.72	$ 120,250
Lucy Lu, M.D. Ph.D.	2/22/12	225,000	$6.85	$1,523,250
Karin M. Hehenberger, M.D., Ph.D.	4/19/12	125,000	$7.84	$ 763,750
Dale Ritter	2/2/12	30,000	$6.85	$ 203,100

(1) Represents the per share fair market value of our common stock, as determined in good faith by our board of directors on the grant date.

(2) Amounts listed represent the aggregate fair value amount computed as of the grant date of each option and award during 2012 in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 14, *Stock-Based Compensation,* of the Notes to the Financial Statements. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our named executive officers will only realize compensation to the extent the trading price of our common stock is great than the exercise price of such stock options.

(3) Consists of an option to purchase our common stock granted to Dr. Weisman upon his appointment to our board of directors in August 2012.

Outstanding Equity Awards at 2012 Fiscal Year-End

The following table sets forth certain information regarding all outstanding equity awards held by our named executive officers as of December 31, 2012.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date (1)
Bobby W. Sandage, Jr., Ph.D.	100,000	200,000	$1.93	4/12/2021
Noah D. Beerman	75,000	150,000	2.95	9/25/2021
Lucy Lu, M.D.	—	225,000	$6.85	2/22/2022
Karin M. Hehenberger, M.D., Ph.D.	—	125,000	$7.84	4/19/2022
Karin M. Hehenberger, M.D., Ph.D.	33,333	66,667	$6.00	12/18/2021
Dale Ritter	40,000	80,000	$1.93	5/15/2021
Dale Ritter	—	30,000	$6.85	2/22/2022
Harlan Weisman, M.D. (2)	—	25,000	—	—

(1) 1/3rd of the total of number of shares subject to each option vest on each anniversary of the applicable grant.
(2) Consists of an option to purchase 25,000 shares of our common stock granted to Dr. Weisman upon his appointment to our board of directors in August 2012.

Option Exercises and Stock Vested

Our named executive officers did not exercise any stock option awards during the year ended December 31, 2012.

Pension Benefits

None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us.

Non-Qualified Deferred Compensation

None of our named executive officers participate in or have account balances in qualified or non-qualified defined contribution plans or other nonqualified compensation plans sponsored by us.

Equity Incentive Plans

2007 Stock Incentive Plan

Our board of directors adopted and our stockholders approved our 2007 Plan in June 2007 and January 2008, respectively. As of December 31, 2012, 138,040 shares of common stock have been issued under the 2007 Plan pursuant to the exercise of options, 1,517,960 shares, net of cancellations, of common stock were issued as restricted stock awards under the 2007 Plan, 2,657,110 options to purchase shares of common stock, net of cancellations, were granted and options to purchase an aggregate of 2,519,070 shares of common stock were outstanding.

The purpose of the 2007 Plan is to provide us with the flexibility to use shares, cash, options or other awards based on our common stock as part of an overall compensation package to provide performance-based compensation to attract and retain qualified personnel. We believe that awards under the 2007 Plan may serve to broaden the equity participation of key employees and further link the long-term interests of management and stockholders. Awards under the 2007 Plan may include shares, cash, options, stock appreciation rights, or a similar right with a fixed or variable price related to the fair market value of the shares and with an exercise or conversion privilege related to the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions. 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.

There are 6,000,000 shares of common stock reserved for issuance under the 2007 Plan, of which 1,824,930 shares were available for issuance as of December 31, 2012.

Administration

The 2007 Plan is administered by our board of directors or a committee designated by the board of directors. With respect to grants of awards to our officers or directors, the 2007 Plan is administered by our board of directors or a designated committee in a manner that permits such grants to be exempt from Section 16(b) of the Exchange Act. Grants of awards to covered employees as defined under Section 162(m) of the Code will be made only by a committee comprised solely of two or more directors eligible to serve on a committee making awards. The board of directors has the full authority to select recipients of the grants, determine the extent of the grants, establish additional terms, conditions, rules or procedures to accommodate rules or laws of applicable non-U.S. jurisdictions, adjust awards and to take any other action deemed appropriate; however, no action should be taken that is inconsistent with the terms of the 2007 Plan.

Available Shares

Subject to adjustment upon certain corporate transactions or events, a maximum of 6,000,000 shares of our common stock may be issued under the 2007 Plan. In addition, subject to adjustment upon certain corporate transactions or events, a participant in the 2007 Plan may not receive awards with respect to more than 1,000,000 shares of common stock in any year (and an additional 500,000 shares in connection with a grantee's commencement of continuous service). Any shares covered by an award which is forfeited, canceled or expires shall be deemed to have not been issued for purposes of determining the maximum aggregate number of shares which may be issued under the 2007 Plan, except that the maximum aggregate number of shares which may be issued pursuant to the exercise of incentive stock options shall not exceed 6,000,000. Shares that actually have been issued under the 2007 Plan pursuant to an award shall not be returned to the 2007 Plan and shall not become available for future issuance under the 2007 Plan. To the extent not prohibited by the listing requirements of any established stock exchange or national market system on which our common stock may be traded and any applicable law, any shares covered by an award which are surrendered (i) in payment of the award exercise or purchase price or (ii) in satisfaction of tax withholding obligations incident to the exercise of an award shall be deemed not to have been issued for purposes of determining the maximum number of shares which may be issued pursuant to all awards under the 2007 Plan, unless otherwise determined by the plan administrator.

Eligibility and Types of Awards

The 2007 Plan permits us to grant stock awards, including stock options to our employees, directors and consultants and the employees, directors and consultants of PBS and its affiliates. A stock option may be an incentive stock option, within the meaning of section 422 of the Code, or a nonstatutory stock option. However, only employees may be granted incentive stock options.

Stock Options

Incentive and nonstatutory stock options are granted pursuant to option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2007 Plan, provided that the exercise price of a stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2007 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of the stock options granted under the 2007 Plan, up to a maximum of 10 years, except in the case of certain incentive stock options, as described below. Unless the terms of an

optionholder's stock option agreement provide otherwise, if an optionholder's relationship with us, or any of our affiliates, ceases for any reason other than disability or death, the optionholder may exercise any options vested as of the date of termination but only during the post-termination exercise period designated in the optionholder's stock option agreement. The plan administrator may determine such other portion of the optionholder's unvested award that may be exercised during the post-termination exercise period. The optionholder's stock option agreement may provide that upon the termination of the optionholder's relationship with us, for cause, the optionholder's right to exercise its options shall terminate concurrently with the termination of the relationship. If an optionholder's service relationship with us, or any of its affiliates, ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or beneficiary may exercise any vested options for a period of 12 months. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws or such longer period as specified in the stock option agreement but in no event beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (a) cash or check, (b) surrender of a promissory note acceptable to the plan administrator (subject to minimum interest provisions set forth in the 2007 Plan) (c) a broker-assisted cashless exercise, (d) the tender of common stock previously owned by the optionholder, (e) a net exercise of the option, (f) past or future services rendered and (g) any other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Incentive stock options may be granted only to our employees. The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to incentive stock options that are exercisable for the first time by an optionholder during any calendar year under the 2007 Plan may not exceed $100,000. No incentive stock option may be granted to any employee who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of the total combined voting power or that of any of our affiliates unless (a) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (b) the term of the incentive stock option does not exceed five years from the date of grant.

Corporate Transactions

Effective upon the consummation of a corporate transaction, all outstanding awards under the 2007 Plan shall terminate. However, all such awards shall not terminate to the extent they are assumed in connection with the corporation transaction.

The plan administrator shall have the authority, exercisable either in advance of any actual or anticipated corporate transaction or change in control or at the time of an actual corporate transaction or change in control and exercisable at the time of the grant of an award under the 2007 Plan or any time while an award remains outstanding, to provide for the full or partial automatic vesting and exercisability of one or more outstanding unvested awards under the 2007 Plan and the release from restrictions on transfer and repurchase or forfeiture rights of such awards in connection with a corporate transaction of change in control, on such term and conditions as the plan administrator may specify. The plan administrator shall also have the authority to condition any such award vesting and exercisability or release from such limitations upon the subsequent termination of the continuous service of the holder of the award within a specified period following the effective date of the corporate transaction or change in control. The plan administrator may provide that any awards so vested or released from such limitations in connection with a change in control, shall remain fully exercisable until the expiration or sooner termination of the award. Our executive officers' employment agreements provide for acceleration of vesting under certain conditions, see "Other Compensation, Potential Payments Upon Termination or Change in Control."

Amendment and Termination

Our board of directors may amend, suspend or terminate the 2007 Plan as it deems advisable, except that it may not amend the 2007 Plan in any way that would adversely affect a participant with respect to an award previously granted. In addition, our board of directors may not amend the 2007 Plan without stockholder approval if such approval is then required pursuant to Section 422 of the Code, the regulations promulgated thereunder or the rules of any stock exchange or similar regulatory body.

Stock Awards and Restricted Stock

A stock award consists of the transfer by us to a participant of shares of common stock. The consideration for the shares to be issued shall be determined by the plan administrator. Shares of common stock acquired pursuant to a stock award may, but need not be, subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator.

Other Awards

In the case of other awards granted under the 2007 Plan, the administrator has the authority to determine the exercise or purchase price, if any.

Employee Stock Purchase Plan

On December 19, 2011, our board of directors approved the 2012 Coronado Employee Stock Purchase Plan, or the ESPP, providing for the issuance of up to 200,000 shares of common stock to eligible employees, including our executive officers, subject to stockholder approval of the ESPP. Eligible employees can purchase our common stock at the end of a predetermined offering period at a price equal to 85% of the lesser 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 resulting in 21,644 shares issued. Thereafter, offerings will be six months in duration and will commence on December 1 and June 1 of each year. Employee contributions will be made through payroll deductions throughout the offering period and, subject to certain limitations, will be used to purchase shares at the end of each offering period. As of December 31, 2012, 178,356 shares were available for issuance under the ESPP. The ESPP is compensatory and will result in stock-based compensation expense.

Non-Executive Director Compensation

The following table and related footnotes show the compensation paid to or accrued for the benefit of our non-executive directors during the fiscal year ended December 31, 2012.

Name	Fees Earned or paid in Cash (1)	Option Awards (2)	All Other Compensation (3)	Total
David J. Barrett	$37,500	$102,750	$ —	$140,250
Glenn L. Cooper, M.D.	30,000	308,250	330,000	668,250
J. Jay Lobell	47,500	102,750	—	150,250
Jimmie Harvey, M.D.	35,000	102,750	—	137,750
Michael W. Rogers	55,000	102,750	—	157,750
Lindsay A. Rosenwald, M.D.	40,000	102,750	—	142,750
Eric K. Rowinsky, M.D.	30,000	102,750	250,000	382,750

(1) Represents director and committee fees accrued in or paid for 2012.

(2) Amounts listed represent the aggregate fair value amount computed as of the grant date of each option and award during 2012 in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 13, *Stock-Based Compensation*, of the Notes to the Consolidated Financial Statements. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures

related to service-based vesting conditions. Our directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options. The aggregate number of shares subject to outstanding option awards as of December 31, 2012 was 15,000 shares, with the exception of a 25,000 share award made to Dr. Weisman upon his appointment to the board of directors in 2012 and 45,000 granted to Dr. Cooper, as Chairman of the board. 1/3 of the total of number of shares subject to all options vest on each annual anniversary of the applicable grant date for so long each of the board members continue to serve on our board of directors. For Dr. Cooper, includes an option to purchase 25,000 shares of our common stock, granted in connection with his consulting agreement.

(3) For Dr. Cooper, represents $300,000 earned and paid in 2012 pursuant to his employment arrangement and $30,000 of severance that will be paid during 2013; for Dr. Rowinsky, represents amount earned and paid in 2012 pursuant to his consulting arrangement.

In October 2010, our board of directors adopted a compensation program for our non-employee directors, or the Non-Employee Director Compensation Policy. Pursuant to the Non-Employee Director Compensation Policy, each member of our board of directors who is not our employee and who is not otherwise receiving compensation from us pursuant to another arrangement, will receive an annual cash retainer of $30,000, payable quarterly, and will receive an initial option grant to purchase up to 25,000 shares of our common stock. Such stock options vest in three annual installments. In July 2011, the Non-Employee Director Compensation Policy was modified to include additional fees for committee participation whereby committee members and committee chairs will receive additional annual cash retainers of $5,000 and $10,000, respectively, payable quarterly. The Non-Employee Director Compensation Policy was further amended in February 2012 by providing for annual option grants.

Our amended and restated certificate of incorporation limits the liability of our directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to the corporation or its stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. These limitations also do not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Our amended and restated bylaws provide that we will indemnify our directors and executive officers, and may indemnify other officers, employees and other agents, to the fullest extent permitted by law. Our amended and restated bylaws also provide that we may advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by us and secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our amended and restated bylaws permit such indemnification. We have obtained a directors' and officers' liability insurance policy.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers, or

any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

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

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

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth, as of December 31, 2012, certain information related to our compensation plans under which shares of our common stock are authorized for issuance.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by stockholders	2,519,070	$3.37	1,824,930
Equity compensation plans not approved by stockholders	1,207,433	$5.81	—
Total	3,726,503		1,824,930

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth, as of March 8, 2013, certain information concerning the beneficial ownership of our common stock by (i) each stockholder known by us to own beneficially five percent or more of our outstanding common stock; (ii) each director; (iii) each named executive officer; and (iv) all of our executive officers and directors as a group, and their percentage ownership and voting power.

Name and Address of Beneficial Owner[1]	Shares Beneficially Owned[2]	Percentage Beneficially Owned[3]
Elliott Associates, L.P.[4]	3,731,279	14.3%
Lindsay A. Rosenwald, M.D.[5]	3,594,511	13.8%
RA Capital Management, LLC[6]	1,775,154	6.8%
LAR Family Trusts[7]	1,464,869	6.8%
Brookline Investments Inc.[8]	1,352,825	5.2%
J. Jay Lobell[9]	346,066	1.3%
Bobby W. Sandage, Jr., Ph.D.[10]	325,311	1.2%
Noah Beerman[11]	85,000	*
Dale Ritter[12]	60,000	*
Lucy Lu, M.D.[13]	85,000	*
Karin Hehenberger, M.D., Ph.D.[14]	95,925	*
Eric K. Rowinsky, M.D.[15]	133,993	*
Jimmie Harvey, Jr. M.D.[16]	21,667	*
Michael W. Rogers[17]	13,333	*
David J. Barrett[18]	13,333	*
Harlan Weisman[19]	20,000	*
All officers and directors as a group (12 persons)	**4,794,139**	**18.4%**

* Less than 1%.

(1) Unless otherwise indicated, the address of such individual is c/o Coronado Biosciences, Inc., 24 New England Executive Park, Burlington, Massachusetts 01803.

(2) Includes common stock, as well as options that are exercisable during the 60-day period following March 8, 2013.

(3) Based upon 26,023,484 shares of common stock issued and outstanding as of March 8, 2013.

(4) Based on information contained in Schedule 13G/A filed with the SEC on June 26, 2012 by Elliott Associates, L.P. ("Elliott Associates"), Elliott International, L.P. ("Elliott International") and Elliott International Capital Advisors Inc. ("International Advisors"). Includes 792,328 shares of common stock held directly by Elliott Associates, 1,284,053 shares of common stock held directly by Manchester Securities Corp., a wholly owned subsidiary of Elliott Associates ("Manchester") and 1,654,898 shares of common stock held directly by Elliott International and indirectly by International Advisors. Manchester's address is 712 Fifth Avenue, New York, New York 10019. On Schedule 13G/A, Elliott Associates, Elliott International and International Advisors did not list any natural persons having voting and/or dispositive powers over the shares held of record by the company.

(5) Includes 3,594,511 shares of common stock, 2,659,001 shares of which are held directly by Dr. Rosenwald, 170,983 shares of which are held by Capretti Grandi, LLC, 742,861 shares of which are held by PBS, and 21,666 shares of which are issuable upon the exercise of options exercisable within 60 days of March 8, 2013. Dr. Rosenwald has voting and dispositive control over the shares held by Capretti Grandi, LLC and PBS. Does not include (i) 453,822 shares of common stock held by the LAR Family Trusts and the Lindsay A. Rosenwald M.D. 2000 Family Trust (ii) 11,047 shares of common stock underlying warrants held by the LAR Family Trusts, or (iii) 1,000,000 shares of common stock held by trusts established for the benefit of Dr. Rosenwald's family, over which Dr. Rosenwald does not have any voting or dispositive control.

(6) Based on information contained in Schedule 13G/A filed with the SEC on February 14, 2013 by RA Capital Management, LLC ("Capital"), Peter Kolchinsky and RA Capital Healthcare Fund, L.P. ("Fund"). Includes

983,382 shares of common stock held directly by the Fund and 1,735,597 shares of common stock held indirectly by: (i) Capital, as the investment adviser and sole general partner of the Fund and investment adviser to an account owned by a separate investment vehicle, and (ii) Mr. Kolchinsky as the manager of Capital. Mr. Kolchinsky, by virtue of his position as manager of Capital, has the sole authority to vote and dispose of all shares of common stock held by the Fund and Capital. The principal business office of the Fund, Capital and Mr. Kolchinsky is 20 Park Plaza, Suite 1200, Boston, MA 02116.

(7) Mr. Gross is the trustee of four trusts established for the benefit of Lindsay Rosenwald and his family, which own an aggregate of 1,000,000 shares of our capital stock as follows: (a) Lindsay A. Rosenwald 2000 Irrevocable Indenture of Trust dated May 24, 2000 (Delaware) owns 720,000 shares of common stock; (b) Lindsay A. Rosenwald Alaska Irrevocable Indenture of Trust dated August 28, 2001 owns 80,000 shares of common stock; (c) Lindsay A. Rosenwald Nevada Irrevocable Indenture of Trust dated January 6, 2003 owns 100,000 shares of common stock; and (d) Lindsay A. Rosenwald Rhode Island Irrevocable Indenture of Trust dated August 28, 2001 owns 100,000 shares of common stock. Mr. Gross may be deemed to beneficially own the shares held by these trusts because he has sole voting and dispositive control over all shares held by these trusts. Mr. Gross's address is c/o AmTrust Financial Services, 59 Maiden Lane, 6th Floor, New York, NY 10038**.**

(8) These shares are held by Brookline Coronado Investment Fund LLC, CSA Biotechnology Fund I, LLC and CSA Biotechnology Fund II (collectively, "Brookline"). The address of these entities is c/o Brookline Investments, Inc., 2501 Twentieth Place South, Suite 275, Birmingham, AL 35223. Mr. Rainer Twiford has voting and dispositive power over these shares.

(9) Includes 346,066 shares of common stock, 321,000 shares of which are held directly by Mr. Lobell, 21,667 shares of which are issuable upon the exercise of options exercisable within 60 days of March 8, 2013 and 3,399 shares of which are issuable upon the exercise of warrants exercisable within 60 days of March 8, 2013.

(10) Includes 325,311 shares of common stock, 15,311 shares of which are held directly by Dr. Sandage and 300,000 shares of which are issuable upon the exercise of options exercisable within 60 days of March 8, 2013.

(11) Includes 85,000 shares of common stock, 10,000 shares of which are held directly by Mr. Beerman and 75,000 shares of which are issuable upon the exercise of options exercisable within 60 days of March 8, 2013.

(12) Includes 60,000 shares of common stock, 5,000 shares of which are held jointly by Mr. Ritter and his spouse and 50,000 shares of which are issuable upon exercise of options exercisable within 60 days of March 8, 2013.

(13) Includes 85,000 shares of common stock, 10,000 shares of which are held directly by Dr. Lu and 75,000 shares of which are issuable upon exercise of options exercisable within 60 days of March 8, 2013.

(14) Includes 95,925 shares of common stock, 20,925 shares of which are held directly by Dr. Hehenberger and 75,000 shares of which are issuable upon exercise of options exercisable within 60 days of March 8, 2013.

(15) Includes 133,993 shares of common stock, all of which are issuable upon exercise of options exercisable within 60 days of March 8, 2013.

(16) Includes 21,667 shares of common stock, all of which are issuable upon exercise of options exercisable within 60 days of March 8, 2013.

(17) Includes 13,333 shares of common stock, all of which are issuable upon exercise of options exercisable within 60 days of March 8, 2013.

(18) Includes 13,333 shares of common stock, all of which are issuable upon exercise of options exercisable within 60 days of March 8, 2013.

(19) Includes 20,000 shares of common stock held directly by Dr. Weisman.

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

Five of our directors, Michael W. Rogers, David J. Barrett, Jimmie Harvey, Jr., J. Jay Lobell and Lindsay A. Rosenwald are independent directors as that term is defined under NASDAQ Marketplace Rules. All of the members of our audit committee, compensation committee and nominating and corporate governance committee are independent.

Transactions with Related Parties

The following is a description of transactions since January 1, 2012 to which we have been a party, in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or beneficial owners of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change-in-control arrangements, which are described under "Executive Compensation."

2012 Underwritten Common Stock Offering

In June 2012, we issued an aggregate of 5,750,000 shares of common stock in our June 2012 Offering, for an aggregate purchase price of $28.8 million. The following table sets forth the number of shares of common stock purchased by our officers, directors and principal stockholders in the June 2012 Offering :

Name	Number of common shares Purchased
Glenn L. Cooper, M.D.	10,000
CSA/Brookline	300,000
Dale and Debra Ritter	5,000
Lindsay A. Rosenwald, M.D.	200,000
Manchester Securities Corp. (2)	2,000,000
RA Capital	1,500,000
J. Jay Lobell	25,000
Bobby W. Sandage, Jr,. Ph.D.	10,000
Noah D. Beerman	5,000
Lucy Lu. M.D.	10,000
Karin M. Hehenberger, M.D., Ph.D.	20,000

(1) Additional detail regarding these stockholders and their equity holdings is provided in "Security Ownership of Certain Beneficial Owners and Management."

(2) Represents 613,438 shares of common stock purchased by Elliot Associates and 1,386,562 shares of common stock purchased by Elliot International.

Asphelia Asset Purchase

In January 2011, we acquired certain assets of Asphelia relating to CNDO-201 pursuant to an asset purchase agreement. The consideration paid for the assets included the assumption of certain Asphelia liabilities and the issuance of 2,525,677 Series B shares. At the time of such acquisition, Mr. Lobell, one of our directors, was the chief executive officer and a director of Asphelia and Dr. Rosenwald, one of our directors and a principal stockholder, was a significant stockholder of Asphelia. One liability assumed from Asphelia was the PCP Note dated January 2009, issued by Asphelia to PCP, an entity affiliated with Dr. Rosenwald and Mr. Lobell, in the principal amount of $750,000. Interest on the PCP Note is at the rate of 10% per annum payable quarterly, in arrears. The outstanding principal and accrued but unpaid interest on the PCP Note was repaid in full in September 2012. We paid $74,000 of interest on the PCP Note in 2012.

We have entered into employment arrangements with our executive officers, as more fully described in "Executive and Director Compensation—Executive Employment Agreements" and "—Potential Payments Upon Termination or Change in Control."

Transactions with Related Persons

The written charter of our audit committee authorizes and the NASDAQ Marketplace Rules require our audit committee to review and approve related party transactions. In reviewing related party transactions, our audit committee applies the basic standard that transactions with affiliates should be made on terms no less

favorable to us than could have been obtained from unaffiliated parties. Therefore, the audit committee reviews the benefits of the transactions, terms of the transactions and the terms available from unrelated third parties, as applicable. All transactions other than compensatory arrangements between us and our officers, directors, principal stockholders and their affiliates will be approved by our audit committee or a majority of the disinterested directors, and will continue to be on terms no less favorable to us than could be obtained from unaffiliated third parties.

Item 14. Principal Accounting Fees and Services.

PricewaterhouseCoopers LLP served as our independent registered public accounting firm for the fiscal years ended December 31, 2012 and 2011. The following table shows the fees that were billed for audit and other services provided by this firm during the fiscal years indicated.

	Years Ended December 31,	
	2012	2011
Audit Fees[1]	$505,500	$506,500
Audit-Related Fees[2]		27,400
Tax Fees[3]	18,300	—
All Other Fees[4]	1,800	—
Total	$525,600	$533,900

(1) *Audit Fees*—This category includes the audit of our annual financial statements, review of financial statements included in our Quarterly Reports on Form 10-Q, and services that are normally provided by independent auditors in connection with the engagement for fiscal years.

(2) *Audit-Related Fees*—This category consists of fees reasonably related to the performance of the audit or review of our financial statements that are not reported as "Audit Fees." Audit related fees of $26,400 related to due diligence for a corporate transaction.

(3) *Tax Fees*—This category consists of tax compliance, tax advice and tax planning work.

(4) *All Other Fees*—This category consists of fees for other miscellaneous items.

Pre-Approval Policies and Procedures of the Audit Committee

The audit committee has adopted policies and practices relating to the approval of all audit and non-audit services that are to be performed by our registered public accounting firm. This policy generally provides that we will not engage our registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by the audit committee or the engagement is entered into pursuant to one of the pre-approval procedures described below. From time to time, the audit committee may pre-approve specified types of services that are expected to be provided to us by our registered public accounting firm during the next 12 months. Any pre-approval is detailed as to the particular service or type of services to be provided and is subject to a maximum dollar amount.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant. (1)
3.2	First Certificate of Amendment of Amended and Restated Certificate of Incorporation. (1)
3.3	Certificate of Designation, Preferences and Rights of the Series B Preferred Stock. (1)
3.4	Certificate of Designation, Preferences and Rights of the Series C Preferred Stock. (1)
3.6	Amended and Restated Bylaws of the Registrant. (1)
4.1	Form of Common Stock Certificate. (1)
4.2	Form of Series A Preferred Stock Certificate. (1)
4.3	Form of Series B Preferred Stock Certificate. (1)
4.4	Form of Series C Preferred Stock Certificate. (1)
4.5	Form of Warrant for the Purchase of Shares of Common Stock issued by the Registrant in connection with the 2008 bridge financing. (1)
4.6	Form of Warrant for the Purchase of Shares of Common Stock issued by the Registrant in connection with the 2009 bridge financing. (1)
4.7	Form of Warrant for the Purchase of Shares of Common Stock issued by the Registrant in connection with the Series A financing. (1)
4.8	Form of Series C Convertible Preferred Stock Purchase Warrant issued by the Registrant in connection with the 2011 Series C financing. (1)
4.10	Form of Consultant/Agent Warrant to Purchase Common Stock. (1)
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. (2)
10.1	Form of Note Purchase Agreement relating to the 2008 bridge financing. (1)
10.2	Form of Note Purchase Agreement relating to the 2009 bridge financing. (1)
10.3	Form of Subscription Agreement relating to the initial Series A financing. (1)
10.4	Form of Subscription Agreement relating to the second Series A financing. (1)
10.5	Form of Subscription Agreement relating to the Series C financing. (1)
10.6	Form of Consent and Support Agreement. (1)
10.7	Letter Agreement, dated April 29, 2011, by and between Manchester Securities Corp. and the Registrant. (1)
10.8*	2007 Stock Incentive Plan. (1)
10.9*	Form of 2007 Stock Incentive Plan and Award Agreement. (1)
10.10†	Exclusive Sublicense Agreement, effective as of December 12, 2005, by and between Ovamed GmbH & Co KG and Collingwood Pharmaceuticals, Inc. (1)

Exhibit Number	Description
10.11†	Manufacturing and Supply Agreement, dated March 29, 2006, by and among Collingwood Pharmaceuticals, Inc. and Ovamed GmbH. (1)
10.12†	Licence Agreement, dated November 5, 2007, between UCL Business PLC and the Registrant. (1)
10.13†	Letter Agreement, dated November 8, 2007, by and between Asphelia Pharmaceuticals, Inc. and Ovamed GmbH. (1)
10.14†	Amendment No. 1 to License Agreement, effective as of September 30, 2009, by and between the Registrant and UCL Business PLC. (1)
10.15†	Master Contract Services Agreement, effective as of April 1, 2010, by and between the Registrant and Progenitor Cell Therapy, LLC. (1)
10.16†	Term Sheet in causa Ovamed/Asphelia, dated June 8, 2010, by and between Ovamed GmbH and Asphelia, Inc. (1)
10.17†	Amendment and Agreement, dated January 7, 2011, by and among Asphelia Pharmaceuticals, Inc., the Registrant and OvaMed GmbH. (1)
10.18	Asset Purchase Agreement, dated as of January 7, 2011, by and between the Registrant and Asphelia Pharmaceuticals, Inc. (1)
10.19*	Employment Agreement, dated as of March 21, 2011, by and among the Registrant and Bobby W. Sandage, Jr., Ph.D. (1)
10.20*	Employment Agreement, dated as of April 1, 2011, by and among the Registrant and Glenn L. Cooper. M.D. (1)
10.21*	Employment Agreement, dated as of May 16, 2011, by and between the Registrant and Dale Ritter.(1)
10.22*	Separation Agreement, dated June 3, 2011, by and between the Registrant and Gary G. Gemignani. (1)
10.23*	Separation Agreement, dated December 2, 2010, by and between the Registrant and Raymond J. Tesi, M.D. (1)
10.24*	Consulting Agreement, entered into as of September 21, 2010, by and between the Registrant and Eric Rowinsky, M.D. (1)
10.25	Form of Indemnification Agreement by and between the Registrant and its officers and directors. (1)
10.26	Lease Agreement dated May 26, 2011 relating to the Registrant's premises located at 15 New England Executive Park, Burlington, Massachusetts 01803. (1)
10.27	Master Contract Services Agreement, as of March 12, 2008, by and between the Registrant and BioReliance Corporation. (1)
10.28	Consulting Agreements between the Registrant and each of Mark Lowdell, Ph.D. and UCL Consultants Limited. (1)
10.29	10% Senior Promissory Note, as amended, issued by Asphelia Pharmaceuticals, Inc. to Paramount Credit Partners, LLC. (1)
10.30*	Employment Agreement, effective as of September 26, 2011, by and between the Registrant and Noah D. Beerman. (3)
10.31	Consulting Agreement, as of September 27, 2011, by and between the Registrant and Joel Weinstock, M.D. (4)

Exhibit Number	Description
10.32	Terms of Agreement, effective as of December 22, 2011, by and among the Registrant, OvaMed GmbH and Dr. Falk Pharma GmbH. (5)
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. (5)
10.34	Side Agreement, effective as of November 15, 2011, by and between the University of Iowa Research Foundation, OvaMed GmbH and the Registrant. (4)
10.35*	Employment Agreement, made and entered into on February 21, 2012, by and between the Registrant and Lucy Lu, M.D. (6)
10.36†	Collaboration Agreement, dated as of March 20, 2012, between the Registrant, OvaMed GmbH and Dr. Falk Pharma GmbH. (7)
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)
10.38†	Amendment No. 2 to License Agreement, effective as of May 16, 2012, by and between the Registrant and UCL Business PLC. (9)
10.39	Loan and Security Agreement, dated as of August 28, 2012, by and between the Registrant and Hercules Technology Growth Capital, Inc. (10)
10.40	At Market Issuance Sales Agreement, dated as of October 5, 2012, by and between the Registrant and MLV & Co. LLC. (11)
10.41††	Second Amendment and Agreement, dated as of December 21, 2012, by and between the Registrant and Ovamed GmbH.
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.
10.43*	Second Amendment to Employment Agreement, dated as of December 28, 2012, by and between the Registrant and Bobby W. Sandage, Jr.
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.
10.45††	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.
14.1	Code of Ethics of Coronado Biosciences, Inc. applicable to Directors, Officers and Employees. (12)
21.1	Subsidiaries of the Registrant. (1)
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page of this Form 10-K).
31.1	Certification of Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley act of 2002.
101.INS	XBRL Instance Document. (13)
101.SCH	XBRL Taxonomy Extension Schema Document. (13)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document. (13)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document. (13)
101.LAB	XBRL Taxonomy Extension Label Linkbase Document. (13)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document. (13)

† Confidential treatment has been granted with respect to portions of this exhibit.
†† Confidential treatment has been requested with respect to portions of this exhibit.
* Indicates management contract or compensatory plan.
(1) Filed as an exhibit with the same number to the Registrant's Registration Statement on Form 10-12G (File No. 000-54463) initially filed on July 15, 2011.
(2) Filed as exhibit 4.10 to the Registrant's Current Report on Form 8-K filed on August 29, 2012.
(3) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on September 26, 2011.
(4) Filed as an exhibit with the same number to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-177041) filed on October 7, 2011.
(5) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on December 22, 2011.
(6) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on February 23, 2012.
(7) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on March 23, 2012.
(8) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on April 25, 2012.
(9) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on May 25, 2012
(10) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on August 29, 2012.
(11) Filed as exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on October 5, 2012.
(12) Filed as an exhibit with the same number to the Registrant's Registration Statement on Form S-1 (File No. 333-177041) filed on September 28, 2011.
(13) Pursuant to Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Annual Report on Form 10-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to liability of that Section, and shall not be part of any registration statement or other document filed under the Securities Act of the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Coronado Biosciences, Inc. and Subsidiary
(a development stage enterprise)

CONSOLIDATED FINANCIAL STATEMENTS
Index to Financial Statements

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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 subsidiary (a development stage enterprise) at December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, and, cumulatively, for the period from June 28, 2006 (date of inception) to December 31, 2012 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, 2012, based on criteria established in *Internal Control—Integrated Framework* 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 was an integrated audit in 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 18, 2013

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

	December 31, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 40,199	$ 23,160
Prepaid and other current assets	393	215
Total current assets	40,592	23,375
Property & equipment, net	51	—
Other assets	349	—
Total Assets	$ 40,992	$ 23,375
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,029	$ 575
Interest payable—related party	—	19
Interest payable	119	—
Accrued expenses	2,185	2,899
Current portion of note payable	1,799	—
Total current liabilities	5,132	3,493
PCP notes payable—related party	—	750
Note payable	12,386	—
Other long-term liabilities	1,441	—
Total Liabilities	18,959	4,243
Commitments and Contingencies (Note 6)		
Stockholders' Equity:		
Convertible Preferred stock, $.001 par value, 584,390 and 587,376 Series C shares authorized, 0 shares issued and outstanding as of December 31, 2012 and 2011, respectively	—	—
Common stock, $.001 par value, 50,000,000 shares authorized, 24,400,754 and 18,604,245 shares issued and outstanding as of December 31, 2012 and 2011, respectively	24	19
Additional paid-in capital	106,193	75,687
Deficit accumulated during development stage	(84,184)	(56,574)
Total Stockholders' Equity	22,033	19,132
Total Liabilities and Stockholders' Equity	$ 40,992	$ 23,375

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

CORONADO BIOSCIENCES, INC. AND SUBSIDIARY
(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,
	2012	2011	2010	2012
Operating expenses:				
Research and development	$ 17,468	$ 8,583	$ 8,341	$ 42,009
General and administrative	8,665	5,755	900	16,279
In-process research and development	1,043	20,706	—	21,749
Loss from operations	(27,176)	(35,044)	(9,241)	(80,037)
Interest income	236	165	61	480
Interest expense	(670)	(74)	(1,535)	(3,953)
Other income	—	—	733	733
Warrant expense	—	(1,407)	—	(1,407)
Net loss	(27,610)	(36,360)	(9,982)	(84,184)
Common stock dividend to Series A Convertible Preferred stockholders	—	(5,861)	—	(5,861)
Net loss attributed to Common stockholders	$ (27,610)	$ (42,221)	$ (9,982)	$(90,045)
Basic and diluted net loss per common share	$ (1.27)	$ (5.51)	$ (2.24)	
Weighted average common shares outstanding—basic and diluted	21,654,984	7,662,984	4,453,786	

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

CORONADO BIOSCIENCES, INC. AND SUBSIDIARY

(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, 2012

($ in thousands except for share amounts)

	Preferred Stock		Common stock		Additional paid-in capital	(Deficit) accumulated during development stage	Total stockholders' Equity
	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 SUBSIDIARY

(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, 2012

($ in thousands except for share amounts)

	Preferred Stock		Common stock		Additional paid-in capital	(Deficit) accumulated during development stage	Total stockholders' Equity
	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
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	—	18	—	18
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

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

CORONADO BIOSCIENCES, INC. AND SUBSIDIARY
(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,
	2012	2011	2010	2012
Cash flows from operating activities:				
Net loss	$(27,610)	$(36,360)	$ (9,982)	$(84,184)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	3,638	1,469	2,329	7,512
Acquired in-process research and development	1,043	20,706	—	21,749
Noncash interest expense	130	—	393	1,898
Noncash interest expense—related parties	—	—	34	286
Contribution of services by stockholder	—	30	40	130
Issuance of Common stock to non-employee for services	—	—	121	121
Change in fair value of common stock warrant liability	—	—	234	234
Change in fair value of embedded conversion feature	—	—	831	831
Change in fair value of preferred stock warrant liability	—	1,407	—	1,407
Depreciation expense	3	22	5	44
Changes in operating assets and liabilities:				
Prepaid and other assets	(238)	(160)	(51)	(453)
Interest payable—related parties	(19)	19	(38)	—
Interest payable	119	—	—	119
Accounts payable and accrued expenses	(260)	1,915	407	3,214
Net cash used in operating activities	(23,194)	(10,952)	(5,677)	(47,092)
Cash flows from investing activities:				
Purchase of office equipment	(54)	—	(13)	(95)
Deposit for leasehold improvements	(225)	—	—	(225)
Purchase of in-process research and development	—	(3,843)	—	(3,843)
Net cash used in investing activities	(279)	(3,843)	(13)	(4,163)
Cash flows from financing activities:				
Proceeds from PCP notes payable—related party	—	—	—	570
Payment of PCP notes payable—related party	—	—	(570)	(570)
Payment of PCP notes payable—Asphelia asset purchase	(750)	—	—	(750)
Proceeds from notes payable—related parties	—	—	302	2,221
Proceeds from issuance of Series A Convertible Preferred Stock	—	—	21,681	21,681
Payment of costs related to the issuance of Series C Convertible Preferred Stock	—	—	(2,291)	(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)	(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	28,855	193	—	29,053
Payment of costs related to the issuance of Common stock	(2,305)	—	—	(2,305)
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	40,512	23,093	19,042	91,454
Increase in cash and cash equivalents	17,039	8,298	13,352	40,199
Cash and cash equivalents—beginning of period	23,160	14,862	1,510	—
Cash and cash equivalents—end of period	$ 40,199	$ 23,160	$14,862	$ 40,199

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

Coronado Biosciences, Inc. and Subsidiary
(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,
	2012	2011	2010	2012
Supplemental disclosure of cash flow information:				
Cash paid for interest	$421	$ 53	$ 81	$ 562
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	$ 621
Conversion of Senior Convertible Notes into Convertible Preferred Stock Series A	$—	$ —	$8,601	$ 8,601
Conversion of notes payable—related parties into Convertible Preferred Stock Series A	$—	$ —	$1,907	$ 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

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 focused on the development of novel immunotherapy biologic agents for the treatment of autoimmune diseases and cancer.

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.

The Company has incurred losses and experienced negative operating cash flows since inception and has an accumulated deficit of $84.2 million as of December 31, 2012. 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 12) 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. From January 1, 2013 through March 8, 2013, we issued 1,426,250 shares of common stock pursuant to the Sales Agreement and received net proceeds of $10.5 million.

The Company expects to incur substantial expenditures in the foreseeable future for the research, development and potential commercialization of its product candidates. Management believes that cash and cash equivalents on hand, including cash raised from the public offering in June 2012 (see Note 11) and the term loan with Hercules Technology Growth Capital Inc. ("Hercules") (see Note 10) and the ATM through March 2013 (see Note 17) are sufficient to sustain operations through the first quarter of 2014 based on its existing business plan and given the ability to control the timing of significant expense commitments. The Company will require additional financing to fund operations beyond the first quarter of 2014 and will require additional financing to develop and obtain regulatory approvals for its product candidates, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. The Company will 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.

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 subsidiary, Innmune Limited. 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") and Common stock and Preferred 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 Cash Equivalents and Concentration of Credit Risk

Cash and cash equivalents consist of cash. 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 their estimated useful life of each asset. Leasehold improvements are amortized over the shorter of their 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, 2012 the Company recorded deferred financing costs of $63,000 in other assets in the accompanying balance sheet.

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. 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.

Government Grant

The Company received a grant under the Therapeutic Discovery Project in 2010 for a total of $733,000. The Company accounted for this government grant as other income in the consolidated statement of operations.

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 July 2012, the Financial Accounting Standards Board (FASB) issued ASU No. 2012-02, *Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment* (ASU 2012-02). This newly issued accounting standard allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform a quantitative impairment test for indefinite-lived intangibles other than goodwill. Under that option, an entity would no longer be required to calculate the fair value of an indefinite-lived intangible asset unless the entity determines, based on that qualitative assessment, that it is more likely than not that the fair value of the indefinite-lived intangible asset is less than its carrying amount. This ASU is effective for annual and interim indefinite-lived intangible asset impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted. Adoption of this standard did not have a material impact on the Company's financial position or results of operations.

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. Although the Company is still evaluating the impact of this standard, the Company does not expect this adoption to have a material impact on its financial position or results of operations.

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 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 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,		
($ in thousands except share and per share amounts)	2012	2011	2010
Historical net loss per share:			
Numerator			
Net loss	$ (27,610)	$ (36,360)	$ (9,982)
Common stock dividend to Series A Preferred stockholders	—	(5,861)	—
Net loss attributed to Common stockholders	$ (27,610)	$ (42,221)	$ (9,982)
Denominator			
Weighted-average common shares outstanding—Denominator for basic and diluted net loss per share	21,654,984	7,662,984	4,453,786
Basic and diluted net loss per share attributed to common stockholders	$ (1.27)	$ (5.51)	$ (2.24)

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 are 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,		
	2012	2011	2010
Series A Shares	—	3,796,733	2,617,242
Series B Shares	—	2,158,935	—
Series C Shares	—	1,966,635	—
Unvested restricted Common stock	—	—	322,900
Warrants to purchase Common stock	1,091,558	804,949	261,860
Options to purchase Common stock	2,279,603	1,479,291	296,112
	3,371,161	10,206,543	3,498,114

4. Property and Equipment

Property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	As of December 31, 2012	2011
Computer equipment	3	$10	$ 41
Furniture & fixtures	5	38	—
Leasehold improvements	5	6	—
Total property and equipment		54	41
Less: Accumulated depreciation		(3)	(41)
Property and equipment, net		$51	$—

Depreciation expense for the years ended December 31, 2012, 2011, and 2010 and the period from inception to December 31, 2012 was $3,000, $22,000, $5,000 and $44,000, 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:

($ in thousands)	As of December 31, 2012	2011
Accrued expenses:		
Salaries, bonuses and related benefits	$1,064	$ 493
Severance (see Note 15)	354	—
Professional fees	320	215
Research and development expenses	403	653
Accrued milestone	—	1,500
Other	44	38
Total accrued expenses	$2,185	$2,899
Other long-term liabilities:		
Hercules Note end of term charge (Note 10)	398	—
Ovamed manufacturing rights (Note 14)	1,043	—
Total other long-term liabilities	$1,441	$ —

6. Commitments and Contingencies

Operating Lease Obligations

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. Our contractual leasehold improvement costs associated with this lease approximate $752,000. An initial deposit of $225,000 for these costs was made in December 2012 and is included in other assets in the December 31, 2012 consolidated balance sheet. Minimum lease payments over the term of this lease are $98,000 in 2013, $118,000 in 2014, $118,000 2015, $118,000 in 2016, $118,000 in 2017 and $20,000 in 2018, respectively

In July 2012, the Company entered into a five-year lease for approximately 3,200 square feet of office space in Burlington, Massachusetts 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. Minimum lease payments over the term of this lease are $20,000 in 2012, $81,000 in 2013, $84,000 in 2014, $90,000 in 2015 and $23,000 in 2016, respectively.

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.

The Company recognizes rent expense on a straight-line basis over the non-cancellable lease term. Rent expense for the years ended December 31, 2012, 2011 and 2010 and the period from inception to December 31, 2012 was $93,000, $165,000, $97,000, and $357,000, 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, 2012 and 2011, the Company paid a matching contribution of $85,000 and $77,000, 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 cash and cash equivalents, accounts payable, accrued expenses and other current liabilities. The carrying value of the accrued Ovamed Manufacturing rights license included in long-term liabilities 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, 2012, computed using the effective interest rate method, is $14.8 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"), an affiliate of the Principal Stockholder/Director of the Company, 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

The Principal Stockholder/Director, individually and through certain trusts owned in excess of 10% of the Company's issued and outstanding common stock as of December 31, 2012. In addition, certain trusts established for the benefit of family members of the Principal Stockholder/Director beneficially owned an aggregate of approximately 6.0% of the Company's outstanding capital stock as of December 31, 2012.

National Securities Corporation, placement agent for our Series C Share financing (see Note 11), is a related party to the Principal Stockholder/Director. National Securities Corporation, or National, acted as an underwriter of our June 2012 public offering of common stock. National received related commissions of $187,000 in connection with the offering.

10. Debt

Hercules Debt Agreement

In August 2012, the Company entered into a Loan and Security (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 year ended December 31, 2012, interest expense related to the Hercules loan was $609,000, including $123,000 related to accretion of the debt discount. At December 31, 2012, the current portion of the Hercules Note of $1,799,000 and noncurrent portion of $12,386,000 net of the debt discount of $815,000 was recorded on the Consolidated Balance Sheet. Principal payments for the note are $1,800,000 in 2013, $5,750,000 in 2014, $6,300,000 in 2015 and $1,140,000 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 by the Company's Principal Stockholder/Director. 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 Principal Stockholder/Director.

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 by the Principal Stockholder/ Director. 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. PBC 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:

($ in thousands)	For the Year Ended December 31, 2012	2011	2010	Period from June 28, 2006 (Date of Inception) to December 31, 2012
Interest expense	$609	$—	$ 237	$1,641
Interest expense—related parties	55	74	76	503
Amortization of embedded conversion feature	—	—	831	831
Change in fair value of common stock warrant liability	—	—	234	234
Amortization of deferred financing fees	6	—	157	744
Total interest expense	$670	$ 74	$1,535	$3,953

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, 2012 and 2011, there were no Series A Shares outstanding. See "Conversion of Series A, B and C Shares" below**.**

The terms, rights, preference and privileges of the Series A Shares were as follows:

Voting Rights

Holder of Series A Shares voted together with the common stock on all matters, on an as-converted to common stock basis, and not as a separate class or series (except as otherwise may be required by applicable law). There was no cumulative voting.

Liquidation

In the case of a liquidation event, including a sale, merger or winding up of the Company, the holders of Series A Shares were entitled to receive $12.59 per share (representing 150% of the original issuance price), out of the proceeds of such liquidation, in preference to the holders of common stock.

Conversion

Each share of Series A Shares could voluntarily convert into one share of common stock at the election of the holder. Additionally, each Series A Share would automatically convert into one share of common stock upon the earlier of the following:

(1) April 26, 2012, or

(2) In the event the Company's capital stock becomes publicly traded and reached certain price levels.

In May 2011, the conversion feature was amended such that the Series A Shares would automatically convert to common stock on the effective date of a registration statement covering the resale of the underlying common stock. This conversion occurred on November 15, 2011 upon the effectiveness of the Company's Form S-1.

Dividends

Dividends are payable when and if declared by the Board of Directors. There are no cumulative accruing dividend rights.

The Series A Shares were to automatically convert into common stock on April 26, 2012 and the holders of Series A Shares would have immediately prior to such automatic conversion received a special dividend per share (the "Special Dividend") payable in cash and/or shares of common stock, as determined at the election of, and in the sole discretion of, the Company's board of directors, and only to the extent that such Special Dividend is legally payable by the Company. The value of any shares of common stock issued in payment of the Special Dividend would be determined in the reasonable, good-faith discretion by the Company's board of directors at the time of payment.

The Special Dividend per share of Series A Shares could be paid in cash or in shares of common stock equal to 50% of the offering price, or $4.20. (See Special Dividend Declaration below)

Fully Paid and Nonassessable

All of our outstanding Series A Shares were fully paid and nonassessable.

In addition, under the Company's Certificate of Incorporation, the Board of Directors had the authority, without further action by the stockholders, to issue up to an additional 5,000,000 shares of Preferred Stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. The Company's board of directors could authorize the issuance of additional Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock or Series A Shares.

Special Dividend Declaration

The Company's Board of Directors declared a dividend for an aggregate of 2,178,917 shares of common stock to the holders of Series A Shares in satisfaction of the Special Dividend that would have been due to the Series A Shares on April 26, 2012. In connection with such issuance, the Company (i) eliminated the provision for the Special Dividend due on April 26, 2012 and (ii) amended the event that triggered an automatic conversion of Series A Shares into shares of common stock to be the effective date of a registration statement covering the resale of the underlying common stock. The Special Dividend was declared and paid in May 2011. The estimated fair value of the common stock was $5.9 million, or $2.69 per share.

Series B Shares

On January 7, 2011, the Company issued 2,525,677 Series B Shares related to the Asphelia Asset Purchase. The terms, rights, preference and privileges of the Company's Series B Shares were as follows:

Voting Rights

Holders of Series B Shares voted together with the common stock on all matters, on an as-converted to common stock basis, and not as a separate class or series (except as otherwise may be required by applicable law). There was no cumulative voting.

Liquidation

In the case of a liquidation event, including a sale, merger or winding up of the Company, the holders of Series B Shares would be entitled to receive $8.39 per share (representing 150% of the original issuance price), out of the proceeds of such liquidation, in preference to the holders of common stock.

Conversion

Each Series B Shares would be voluntarily convertible into one share of common stock at the election of the holder. Additionally, each Series B Shares would automatically convert into one share of common stock upon the effective date of a registration statement covering the resale of the underlying common stock. This conversion occurred on November 15, 2011 upon the effectiveness of the Company's Form S-1.

Dividends

Dividends are payable when and if declared by the Board of Directors. There are no cumulative accruing dividend rights.

Fully Paid and Nonassessable

All of the Company's outstanding Series B Shares were fully paid and nonassessable.

Series C Shares

On June 30, 2011, the Company completed an offering of 4,612,624 Series C Shares at $5.59 per share resulting in net proceeds to the Company of approximately $22.9 million. The terms, rights, preference and privileges of the Company's Series C Shares were as follows:

Voting Rights

Holder of Series C Shares voted together with the common stock on all matters, on an as-converted to common stock basis, and not as a separate class or series (except as otherwise may be required by applicable law). There was no cumulative voting.

Liquidation

In the case of a liquidation event, including a sale, merger or winding up of the Company, the holders of Series C Shares would be entitled to receive $8.39 per share (representing 150% of the original issuance price), out of the proceeds of such liquidation, in preference to the holders of common stock.

Conversion

Each Series C Share would be voluntarily convertible into one share of common stock at the election of the holder. Additionally, each Series C Share would automatically convert into one share of common stock upon the effective date of a registration statement covering the resale of the underlying common stock. This conversion occurred on November 15, 2011 upon the effectiveness of the Company's Form S-1. At December 31, 2012 and 2011, there were 584,390 and 587,376 Series C Shares authorized and reserved for issuance of common stock, respectively, including 458,277 and 461,263 shares, respectively, upon exercise of the warrants for Series C Shares originally issued to National Securities Corporation ("NSC"), which Series C Shares will automatically convert to common stock immediately upon exercise of such warrants.

Dividends

Dividends are payable when and if declared by the Board of Directors. There are no cumulative accruing dividend rights.

Fully Paid and Nonassessable

All of the Company's outstanding Series C Shares are fully-paid and nonassessable.

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, 2012 and 2011, the Company had no outstanding Preferred Stock.

Common Stock

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 50,000,000 shares of $0.001 par value common stock.

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.

Compensation expense related to the restricted common stock for the years ended December 2010 and for the period from inception to December 31, 2012 was $2.0 million and $2.1 million, respectively, and was recorded as research and development expense in the consolidated statements of operations. All shares were fully vested as of December 31, 2010.

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.

On October 5, 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 October 2012, the Company issued 3,361 shares of common stock resulting in net proceeds of $19,000.

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 (see Note 11), 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 (see Note 11) 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 will be mark-to-marketed on each valuation date using the Black Scholes pricing model until such time that these awards are 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 will be mark-to-marketed on each valuation date using the Black Scholes pricing model until such time that the award is 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-employee. 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.

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 mark-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.

13. Stock Plans and Stock-Based Compensation

In 2007, the Company's board of directors adopted and stockholders approved the Coronado Biosciences, Inc. 2007 Stock Incentive Plan (the "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 Plan is 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 6,000,000 shares of common stock reserved for issuance under the Plan, of which 4,175,070 were granted, net of cancellations, and 1,824,930 shares were available for issuance as of December 31, 2012.

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 Company determined the risk-free interest rate by using a weighted average assumption equivalent to the expected term based on the U.S. Treasury constant maturity rate.
- *Expected Volatility:* The Company determined its future stock price volatility based on the average historical stock price volatility of comparable peer companies.
- *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 employee groups and the expected effect of

events that have indications on future exercise activity. Expected life for options granted to employees uses the Simplified Method, while option granted to non-employees uses an expected term equal to the life of the contract.

- *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 following assumptions were used:

Stock option plans	2012	2011
Exercise price	$4.75–$7.84	$1.37–$6.00
Expected stock price volatility	87.3%–114.3%	87.5%–92.8%
Risk free rate of interest	0.16%–2.23%	1.17%–2.56%
Expected life of options	2 years–10 years	6 years–10 years

The fair value for non-employee stock based awards are mark-to-marketed 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, 2012, 2011 and 2010, and from the period June 28, 2006 (Date of Inception) to date:

($ in thousands)	2012	2011	2010	Period from June 28, 2006 (Date of Inception) to December 31, 2012
Employee awards	$2,408	$ 520	$ 215	$3,206
Non-employee awards	664	662	2,114	3,413
Non-employee warrants	566	287	—	893
Total compensation expense	$3,638	$1,469	$2,329	$7,512

The following table summarizes stock option activity:

	Outstanding Options			
($ in thousands except per share amounts)	Number of Shares	Weighted Average Exercise Price	Total Weighted Average Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding at December 31, 2011	1,814,070	$2.17	$7,852	9.2
Options granted	730,000	$6.52		
Options exercised	—			
Options forfeited	—			
Options cancelled	25,000	$7.84		
Outstanding at December 31, 2012	2,519,070	$3.37	$2,860	8.54
Options vested and expected to vest	2,519,070	$3.37	$2,860	8.54
Options vested and exercisable	856,047	$1.95	$2,193	8.09

As of December 31, 2012, the Company had unrecognized stock-based compensation expense related to all unvested stock options of $4.4 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 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. Eligible employees began to participate in the ESPP effective February 1, 2012. As of December 31, 2012, 21,644 have been purchased and 178,356 are available for future sale under the ESPP. The Company recognized share-based compensation expense of $95,000 for the year ended December 31, 2012. No prior expense was recognized.

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, which represents 85% of the closing price of common stock on November 30, 2012.

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 Agreement with Ovamed and Falk

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 the 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 $1,500,000 in three equal installments of $500,000 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 to establish a TSO manufacturing facility. Build out and of the manufacturing facility will commence in the first half of 2013 (see Note 6) and continue throughout the year. The Company expects to produce its Phase 3 supplies of TSO from this facility. Ovamed agreed to assist the Company in establishing this facility and the Second Amendment contemplates that the Company and Ovamed 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 Crohn's disease 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 Crohn's disease, 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 Crohn's disease 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 achievement of the related milestones.

Under the Collaboration Agreement, a steering committee comprised of our representatives and representatives of Falk and Ovamed is overseeing the TSO development program in Crohn's disease, 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 Crohn's disease 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.

CNDO—101

In June 2007, the Company entered into a license agreement with GEM Pharmaceuticals, LLC under which the Company received an exclusive, worldwide license to develop and commercialize a family of anthracycline compounds, including the compound CNDO-101, for the treatment of cancer-related conditions. This agreement was terminated by the Company in November 2010.

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

On December 28, 2012, the Company's Board of Directors appointed current director Dr. Harlan F. Weisman, as the Company's new 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 will vest on December 28, 2013 and each annual anniversary thereafter, subject to Dr. Weisman's continued employment with the Company.

On December 28, 2012, the Company's Executive Chairman, Dr. Glenn L. Cooper, resigned 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 will be paid $25,000 per month for 12 months as well as his COBRA premiums for 12 months. The Company also will pay him $30,000 in severance. Dr. Cooper's current options will continue to vest during the term of his consulting agreement and, in addition, all options that have not vested as of December 31, 2013 will automatically vest on that day if he remains in his consulting capacity through that date. 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 will vest on December 28, 2013 if he remains a consultant through that date. 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* 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 has been recognized immediately on December 28, 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 of 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 addition, on December 28, 2012, Dr. Bobby W. Sandage, Jr. became President of the Company and he remains a member of the Board of Directors. Dr. Sandage's change in status from Chief Executive Officer and President to President entitles 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 provides that in the event Dr. Sandage terminates 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. Also on December 28, 2012 the Board of Directors approved the payment to Dr. Sandage of his 2012 performance bonus of $200,000 as well as a retention bonus of $100,000 payable on December 31, 2013, if he remains employed through that date.

The change to Dr. Sandage's existing stock options that provides for full vesting of all unvested options in the event he terminates 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. Further, since the Company determined it was not probable that Dr. Sandage would terminate his employment for "good reason", the Company did not recognize any liability as of December 31, 2012 related to Dr. Sandage's cash severance and COBRA premiums. If Dr. Sandage terminates his employment prior to June 28, 2013, the Company will recognize at that time a liability for his cash severance and COBRA premiums estimated at approximately $435,000. At December 31, 2012, the Company recognized a liability and charge to operations of $200,000 for Dr. Sandage's 2012 performance bonus. Finally, during 2013 the Company will ratably accrue Dr. Sandage's 2013 retention bonus, provided he remains employed with the Company. The Company can provide no assurance that Dr. Sandage will not exercise his right to terminate his employment agreement for good reason prior to June 28, 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 $26.2 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:

($ in thousands)	As of December 31, 2012	2011
Deferred tax assets:		
Net operating loss carryforwards	$ 19,572	$ 13,716
Amortization of up-front fees	3,087	1,214
Amortization of in-process R&D	407	—
Stock compensation	1,522	531
Accruals and reserves	622	846
Tax credits	991	700
Total deferred tax assets	26,201	17,007
Valuation allowance	(26,201)	(17,007)
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, 2012	2011	2010
Percentage of pre-tax income:			
U.S. federal statutory income tax rate	35 %	35 %	35 %
State taxes, net of federal benefit	4 %	5 %	—
Acquired NOL	—	9 %	—
Debt modification costs	—	—	(3)%
Credits	1 %	2 %	—
Non-deductible items	(2)%	(21)%	—
Other (1)	(5)%	(2)%	(1)%
Change in valuation allowance	(33)%	(28)%	(31)%
Effective income tax rate	0 %	0 %	0 %

(1) – Other consists of: 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, 2012 and 2011. 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. The error was determined to be immaterial and 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, the 2011 amounts presented herein have been revised to correct for this misstatement.

As of December 31, 2012, the Company has federal net operating loss carryforwards and research and development tax credit carryforwards of approximately $53.5 million and $1.0 million, including an orphan drug tax credit of $0.3 million, respectively, which expire beginning in 2026 and 2028, respectively. As of December 31, 2012, the Company has state net operating loss carryforwards of approximately $16.8 million, which expires beginning in 2030. 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.

As of December 31, 2012, 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, 2012. The tax years 2006 through 2012 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 extends 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 will be recognized in the period of enactment, which is the first quarter of 2013.

17. Subsequent Events

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 *Trichuris suis* (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 $843,000 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 (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 would will 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 (the "LSA") with Ovamed GmbH ("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 (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 (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.

Proceeds from Stock Issuance under ATM

From January 1, 2013 through March 8 2013, the Company issued 1,426,250 shares of common stock pursuant to the ATM and received net proceeds of $10.5 million.

18. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for fiscal years 2012 and 2011. 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
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)
2011				
Operating expenses	$(22,545)	$(3,736)	$(3,531)	$(5,232)
Other income/(expense)	$ 2	$ 3	$ 166	$(1,487)
Net loss	$(22,543)	$(3,733)	$(3,365)	$(6,719)
Basic and diluted net loss per common share	$ (4.71)	$ (0.64)	$ (0.48)	$ (0.52)

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/ Harlan F. Weisman
Name: Harlan F. Weisman, M.D.
Title: Chief Executive Officer

March 18, 2013

POWER OF ATTORNEY

We, the undersigned directors and/or executive officers of Coronado Biosciences, Inc., hereby severally constitute and appoint Harlan W. Weisman, 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/ Harlan F. Weisman Harlan F. Weisman, M.D.	Chairman of the Board of Directors and Chief Executive Officer (*principal executive officer*)	March 18, 2013
/s/ Lucy Lu Lucy Lu, M.D.	Executive Vice President and Chief Financial Officer (*principal financial officer*)	March 18, 2013
/s/ Dale Ritter Dale Ritter	Senior Vice President, Finance and Chief Accounting Officer (*principal accounting officer*)	March 18, 2013
/s/ Bobby Sandage Bobby W. Sandage, Jr., Ph.D.	President and Director	March 18, 2013
/s/ Eric Rowinsky Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	March 18, 2013
/s/ David Barrett David J. Barrett	Director	March 18, 2013
/s/ Jimmie Harvey, Jr. Jimmie Harvey, Jr., M.D.	Director	March 18, 2013
/s/ J. Jay Lobell J. Jay Lobell	Director	March 18, 2013
/s/ Michael Rogers Michael W. Rogers	Director	March 18, 2013
/s/ Lindsay A. Rosenwald Lindsay A. Rosenwald, M.D.	Director	March 18, 2013

Exhibit 31.1

CORONADO BIOSCIENCES, INC.
CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Harlan F. Weisman, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended December 31, 2012 of Coronado Biosciences, Inc.;

(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 18, 2013

By: /s/ Harlan F. Weisman
Harlan F. Weisman
Chief Executive Officer

Exhibit 31.2

CORONADO BIOSCIENCES, INC.
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, 2012 of Coronado Biosciences, Inc.;

(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 18, 2013

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

Exhibit 32.1

CORONADO BIOSCIENCES, INC.
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, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harlan F. Weisman, Chief Executive Officer, 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 18, 2013

By: /s/ Harlan F. Weisman
Harlan F. Weisman
Chief Executive Officer

Exhibit 32.2

CORONADO BIOSCIENCES, INC.
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, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lucy Lu, Chief Financial Officer, 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 18, 2013

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

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