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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, 2011

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.)**
15 New England Executive Park Burlington, MA	**01803**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 238-6621

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 20, 2012, there were 18,604,245 shares of the registrant's common stock outstanding.

Documents incorporated by reference:

Portions of the Registrant's Proxy Statement relating to the Registrant's Annual Meeting of Stockholders for the year ended December 31, 2011 are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K ("Annual Report") 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;
- uncertainties relating to strategic and collaboration agreements and relationships;
- the early stage of products under development;
- our need for substantial additional funds and uncertainties relating to financings;
- dependence on third party manufacturers;
- government regulation;
- patent and intellectual property matters; 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 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 (*Trichuris suis* ova or CNDO–201) a biologic comprising of the microscopic eggs of the porcine whipworm, for the treatment of autoimmune diseases, such as Crohn's disease ("Crohn's"), ulcerative colitis ("UC") and multiple sclerosis ("MS"); and
- CNDO–109, a compound that activates natural killer ("NK") cells of the immune system to seek and destroy cancer cells, for the treatment of acute myeloid leukemia ("AML").

TSO

In January 2011, in connection with our acquisition of the assets of Asphelia Pharmaceuticals, Inc. ("Asphelia"), we acquired the exclusive rights to TSO in North America, South America and Japan under a sublicense agreement with OvaMed GmbH ("OvaMed"), as well as a manufacturing and supply agreement with OvaMed to provide us with our clinical and commercial requirements for TSO. In December 2011, we entered into a binding Terms of Agreement with OvaMed and Dr. Falk Pharma GmbH ("Falk"), OvaMed's sublicensee in Europe for gastroenterology indications, under which we agreed to collaborate in the development of TSO for Crohn's and, in March 2012, entered into the Collaboration Agreement with OvaMed and Falk.

TSO is the microscopic eggs of a parasitic helminth, or worm, that is found in pigs. TSO is not a human pathogen and is eliminated from the body within several weeks without treatment. Multiple investigator-sponsored clinical trials of TSO for the treatment of Crohn's and UC have been completed in which TSO demonstrated clinical benefit with regard to accepted outcome measurements of remission of disease and was shown to be well tolerated. An Investigational New Drug Application ("IND") was filed with the United States Food and Drug Administration ("FDA") in September 2011 and we initiated a single dose, dose escalation study in patients with Crohn's that was completed in February 2012. The study showed that TSO is safe and well tolerated. Falk is currently conducting a Phase 2 clinical trial in Europe evaluating TSO in Crohn's. An independent data safety monitoring committee will conduct an interim analysis of clinical data early in the second quarter of 2012 and communicate their findings to Falk in the form of a blinded recommendation regarding the trial. Based on current enrollment rates, preliminary results from Falk's Phase 2 clinical trial in Crohn's are currently expected in the first quarter of 2013. We expect to initiate a multi-center Phase 2 clinical trial in Crohn's in the United States in the second quarter of 2012. Assuming positive results from these Phase 2 clinical trials, we expect to collaborate with Falk for future Phase 3 clinical trials in Crohn's to support a submission by us of a Biologic License Application ("BLA") with the FDA.

CNDO–109

In November 2007, we acquired exclusive worldwide rights to develop and market CNDO–109 from the University College London Business PLC ("UCLB"). CNDO–109 is a compound that has been shown to activate NK cells. When activated, NK cells have the ability to differentiate between normal cells and cancer cells, and kill cancer cells by granzyme mediated lysis, a biochemical process whereby the NK cells directly kill cancer cells by destroying their cell membranes and structures.

In vitro preclinical studies conducted at the University College of London 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. Results from the first investigator-sponsored Phase 1 clinical trial of CNDO–109 activated NK cells in eight patients with high-risk AML were presented at the American Society of Hematology (ASH) Annual Meeting on December 13, 2011. 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 investigators observed that the majority of the patients experienced a longer complete remission than their previous complete remission,

In February 2012, we submitted an IND for a multi-center Phase 1/2 clinical trial to evaluate CNDO–109 activated NK cells in patients with relapsed AML. In March 2012, the FDA indicated to us they had no further comments on our IND. We intend to commence this trial in mid-2012 and to use the results of this Phase 1/2 clinical trial to develop a plan for future clinical trials of CNDO–109 to support the filing of a BLA in the United States and similar marketing applications in other countries.

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 to tissues and organs that arise from the loss of tolerance or recognition of "self." Autoimmune disorders include inflammatory bowel

disease ("IBD") such as Crohn's and UC, MS, rheumatoid arthritis, lupus, and type-1 diabetes. According to a 2010 Decision Resources report, in the United States and Japan, the prevalence of Crohn's was 585,000 patients, UC was 712,000 patients and MS was 400,000 patients. 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 by the T helper (Th) cells and suppressed 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*, the majority of Crohn's patients require surgery during their lifetime despite available therapies. Therefore, 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. The need for 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, less frequently administered injectable drugs).

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, 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 behind heart disease. Overall, 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. There are over 30,000 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 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 and MS. 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 parasitic helminth (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 pig 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, a member of our scientific advisory board and certain of his colleagues are currently our consultants.

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)-β, 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 a human host for several weeks before being eliminated from the body without any specific 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, ova are not infective until incubating in the soil for several weeks, thereby preventing direct host-to-host transmission. 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 small 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 ("CDAI") and the Inflammatory Bowel Disease Quality of Life questionnaire ("IBDQ"). Using an IBDQ score $\geq$ 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 $\leq$ 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 $\geq$ 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 three different dosages of TSO in Crohn's. This trial is expected to enroll over 200 patients. An independent data safety monitoring committee will conduct an interim analysis of clinical data early in the second quarter of 2012 and communicate their findings to in the form of a blinded recommendation regarding the trial. Based on current enrollment rates, preliminary results from Falk's Phase 2 clinical trial in Crohn's are currently expected in the first quarter of 2013.

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 (*American Journal of Gastroenterology,* 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 ("SCCAI") were used to determine the efficacy of therapy. Using an IBDQ score $\geq$ 170 to define remission, all three patients had achieved remission by week eight. Using an SCCAI $\leq$ 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 ("UCDAI") $\geq$ 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 $\geq$ 4. Clinical remission, defined as UCDAI $\leq$ 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 ("ITT") (43.3% vs. 16.7%, p = 0.04) and per protocol (PP) (44.8% vs. 17.4%, p = 0.04) populations. Only patients with active disease (UCDAI $\geq$ 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 ("RRMS"). They were given 2500 TSO orally every 2 weeks for 3 months in a baseline versus treatment controlled trial. They showed that the mean number of new gadolinium-enhancing magnetic resonance imaging ("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 2013.

In studies to be presented by Dr. John Fleming and by Dr. Per Soelberg Soerensen, Copenhagen Denmark, at the American Academy of Neurology in New Orleans on April 25, 2012, TSO was used in MS patients with strong safety data. 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.

We are also aware of additional ongoing or planned investigator-initiated clinical trials evaluating TSO in various indications, including MS, UC, and rheumatoid arthritis.

Our Clinical Trial Program

As the result of a pre-IND meeting held among representatives of our company, OvaMed and the FDA, the FDA indicated that no additional pre-clinical studies were required to open the IND in the United States, which was filed with the FDA in September 2011. In February 2012, we announced results from our Phase 1 single dose, dose escalation study in patients with Crohn's.

The Phase 1 clinical trial was a multi-center, sequential dose-escalation, double-blind, placebo-controlled study, the primary objective of which 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 12 patients, with nine patients receiving TSO and three receiving placebo. Primary safety assessments were determined at day 14 post dose.

Overall, TSO was found to be safe and well tolerated across all three dose levels tested. There were only two adverse events (metallic taste and sour taste) that were considered to be study drug related as assessed by the investigators, one which was reported in the 7500 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.

As a result of acceptable tolerance determined by this study, we expect to begin a multicenter Phase 2b study in patients with Crohn's in the second quarter of 2012. Our future clinical trial program in Crohn's will reflect the collaboration and cross-licenses between us and Falk under the Collaboration Agreement, enabling us to use in our regulatory filings data obtained from clinical trials in Crohn's conducted by Falk in Europe. Based on current enrollment rates, preliminary results from the Falk Phase 2 trial are currently expected in the first quarter of 2013. A Steering Committee comprised of representatives of Falk, OvaMed and Coronado will oversee the Crohn's development program, under which we and Falk are expected each to 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 State and Europe.

We also plan to have discussions with the FDA regarding the requirements to initiate a Phase 2 trial in MS patients. In addition, we plan to conduct pilot studies and support certain investigator initiated clinical trials in various other autoimmune diseases.

Manufacturing

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, certificate granted by the European Medicines Agency, or EMA. OvaMed's manufacturing operations will be subject to an FDA inspection to assess compliance with FDA standards. See "Government Regulation and Product Approval."

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 ("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 ("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 ("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 ("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 cryopreservation 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 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. Due to the complex manufacturing requirements, we anticipate developing CNDO–109 activated NK cell therapy using PCT.

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 American Society of Hematology (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 UCL's Phase 1 clinical trial in the United Kingdom. We plan to initiate a Phase 1/2 clinical trial in the United States in mid-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 ("DLT") stopping rules are commonly applied. The 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 are also evaluating selected pilot Phase 1 clinical trials in other tumor types, including multiple myeloma 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 Corporation ("BioReliance") in Maryland. Manufacture and testing of CNDO–109 activated NK cells for our planned Phase 1/2 clinical trial will be conducted at Progenitor™ Cell Therapy, LLC ("PCT"), with facilities in Allendale, NJ and Mountain View, CA. 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 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, the "OvaMed License") and Manufacturing and Supply Agreement dated March 2006, between Asphelia and OvaMed (as amended, 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 (the "Territory"). OvaMed's patent rights arise, in turn, from an exclusive license granted in 2005 by the University of Iowa Research Foundation ("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, 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 the Territory. The OvaMed License terminates upon the expiration of the last licensed patent right, provided that 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.

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 2013 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 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. We agreed that, subject to certain conditions, the IND would initially be submitted by OvaMed and subsequently transferred to us and such transfer was effected in March 2012.

Terms of Agreement and Collaboration Agreement with OvaMed and Falk

In December 2011, we entered into a binding Terms of Agreement with Falk and OvaMed under which we agreed to enter into a collaboration agreement relating to the development of TSO for 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 the Territory. 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, all of which is expected to be paid by the first half of 2013, and a royalty equal to 1% of net sales of TSO in the Territory.

Under the Collaboration Agreement, a Steering Committee comprised of Coronado, Falk and OvaMed representatives will oversee the TSO development program for Crohn's, under which Coronado 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 Coronado 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.

License Agreement with UCL Business PLC

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. Under 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.

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.

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 Progenitor Cell Therapy

In April 2010, we entered into a master contract services agreement (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. Cost of services provided by PCT vary. Through December 31, 2011, we have entered into statements of work with PCT aggregating $1.1 million. This is not an indication of the cost of services we will engage PCT to perform in the future.

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 about 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 pending United States Patent Application Serial No. 11/856,466 and the corresponding national phase applications filed in Australia, Canada, Europe, India and Japan, directed to the method of stimulating natural killer cells using CNDO–109 for the treatment of cancer and other conditions. This patent family has been in-licensed on an exclusive basis from UCLB. The CNDO–109 patents that may issue from this patent family would expire in March 2026 in the absence of any patent term extension.

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 Centocor Ortho Biotech Inc.'s 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 are developing 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 ("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

We do not own or operate manufacturing facilities for the production of TSO or CNDO–109 nor do we plan to develop our own manufacturing operations in the foreseeable future. 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 clinical and commercial requirements of TSO at pre-determined prices. 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.

Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's current good manufacturing practice standards ("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 NDA/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 ("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 independent institutional review board ("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 ("CROs") to administer and conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols and to play a significant role in the subsequent collection and analysis of data from these trials. The failure by any of such third parties to meet expected timelines, adhere to our protocols or meet regulatory standards could adversely impact the subject product development program.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The pharmaceutical product is usually introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer treatments, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The pharmaceutical product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA/BLA or foreign authorities for approval of marketing applications.

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

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

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

United States Review and Approval Processes

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

The NDA/BLA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA/BLA does not satisfy the criteria for approval. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. Drug manufacturers and their subcontractors are required to register

their establishments with the FDA, and are subject to periodic unannounced inspections by the FDA for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our suppliers will be able to comply with the cGMP and other FDA regulatory requirements.

Post-Approval Requirements

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

The FDA also may require 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 U.S. 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.

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.

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.

Item 1A. Risk Factors.

Risks Related to Our Business and Industry

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

Our two product candidates are in the early stage of development and will require substantial further capital expenditures, development, testing, and regulatory clearances prior to commercialization. Of the large number of drugs in development, only a small percentage successfully complete the FDA regulatory approval process and are 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. If we are unable to develop or receive regulatory approval for or successfully commercialize any of our product candidates, we will not be able to generate product revenues.

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 agreement in the event of a material breach by us. Our licenses require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments depends on our ability to generate cash in the future. These agreements generally require us to use diligent and reasonable efforts to develop and commercialize the product candidate. In the case of TSO, OvaMed licenses TSO from a third party, UIRF, in exchange for annual and milestone payments, patent cost reimbursement, royalties based on sales and diligence obligations. Our rights to TSO are, therefore, also subject to OvaMed's performance of its obligations to UIRF, any breach of which we may be required to remedy in order to preserve our rights.

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. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of an NDA or BLA to the FDA and even fewer are approved for commercialization.

Any product candidates we may 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 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. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

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

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

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

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

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale. For example, in phase 1/2 oncology trials, DLT stopping rules are commonly applied. The 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 CROs and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining IRB or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Delays in the completion of clinical testing could result in increased costs to us and delay our ability to 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. 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;
- 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 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.

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

We are completely dependent on third party manufacturers for product supply. In particular, we rely and expect to continue to rely exclusively on OvaMed to supply us with our requirements of TSO. OvaMed is the sole supplier of this product, which it is currently producing at only one facility in Germany, where it also is producing product for clinical trials by third parties, including Falk. If OvaMed becomes unable or unwilling to deliver sufficient quantities of TSO to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there would be a significant interruption of our TSO supply, which would materially adversely affect clinical development and potential commercialization of the product. Similarly, we rely on BioReliance and PCT for our CNDO–109 requirements and our CNDO–109 clinical program would be adversely affected by a significant interruption in the supply of this product. Furthermore, if OvaMed, BioReliance and/or PCT or any other contract manufacturers cannot successfully manufacture material that conforms to our specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for our product candidates. Our third party suppliers will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and intend to maintain product liability insurance relating to our clinical trials, our coverage may not be sufficient to cover claims that may be made against us and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that that may be approved for marketing. Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to the testing and us of 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 may receive the requisite regulatory approval may depend, in part, on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our product candidates to enable us or our collaborators to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

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

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. As a company with a limited number of personnel, we are highly dependent on the development, regulatory, commercial and financial expertise of the members of our senior management, in particular Glenn L. Cooper, M.D. our executive chairman, and Bobby W. Sandage, Jr., Ph.D., our president and chief executive officer. The loss of such individuals or the services of any of our other senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical companies, as well as universities and research organizations. If we are not able to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

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

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

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

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

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

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

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

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

In addition, United States patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, and includes a number of significant changes to United States patent law. These include changes to transition from a “first-to-invent” system to a “first-to-file” system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The United States Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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

Our success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject

matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

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

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

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

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

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

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

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

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

We are a company in the development stage and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses in all periods since our inception in June 2006, including losses of approximately $3.7 million, $10.0 million, and $36.4 million for the years ended December 31, 2009, 2010 and 2011, respectively. At December 31, 2011, we had an accumulated deficit of approximately $56.6 million. We expect to make

substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

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

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2009, 2010 and 2011, we incurred research and development expenses of approximately $2.3 million, $8.3 million and $8.6 million, respectively. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing from contract manufacturers clinical trial materials. We believe that our cash on hand will sustain our operations into the fourth quarter of 2012 and that we will require substantial additional funds to support our continued research and development activities, as well as the anticipated costs of preclinical studies and clinical trials, regulatory approvals and potential commercialization. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our current financial condition raises substantial doubt about our ability to continue as a going concern.

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 and licensing arrangements. We currently have no commitments or agreements relating to any of these types of transactions 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 (collectively, "SOX"), for the year ending December 31, 2012, our management will be required to report on, and our independent registered public accounting firm may be required to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934 (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.

Historically we did not have sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary for, or adequate documented accounting policies and procedures to support effective, internal controls. These material weaknesses contributed to audit adjustments for the years ended December 31, 2010, 2009 and 2008. While we have commenced the process of documenting, reviewing and improving our internal controls over financial reporting for compliance with Section 404 of SOX and have made

efforts to improve our internal controls and accounting policies and procedures, including hiring new accounting personnel and engaging external temporary resources, we may in the future identify deficiencies and weaknesses in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

Risks Associated with our Capital Stock

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

At March 20, 2012, Lindsay A. Rosenwald, M.D., a member of our board of directors, beneficially owned approximately 18.1% of our issued and outstanding capital stock, and certain trusts established for the benefit of Dr. Rosenwald and his family members additionally beneficially owned an aggregate of approximately 7.9% 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.

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

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

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

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

The availability of a substantial number of shares for resale may adversely impact any trading market that may develop for our common stock.

Almost all of our 18.6 million outstanding shares of common stock, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act or an effective registration statement. The availability of a substantial number of shares for resale may adversely impact any trading market that may develop for our common stock.

We have never paid and do not intend to pay cash dividends.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices at 15 New England Executive Park, Burlington, Massachusetts 01803 are occupied under a lease expiring in July 2012 for approximately 600 square feet of space providing for rental payments of approximately $5,200 per month.

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, 2011, 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.

Quarter Ending:	High	Low
Fiscal Year 2011		
Fourth Quarter (November 17 to December 16)	$9.50	$6.00
Fourth Quarter (December 19 to December 31)	$6.50	$6.00

Holders of Record

As of March 20, 2012, there were 515 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.

Item 6. Selected Financial Data.

Not applicable to smaller reporting companies.

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 biopharmaceutical company focused on the development of novel immunotherapy agents for autoimmune diseases and cancer. Our two principal pharmaceutical product candidates in clinical development are:

- TSO, the microscopic eggs of the porcine whipworm, for the treatment of autoimmune diseases, such as Crohn's, UC and MS; and
- CNDO–109, a compound that activates NK cells of the immune system to seek and destroy cancer cells, for the treatment of acute myeloid leukemia.

We acquired the OvaMed License in January 2011 from Asphelia for an aggregate purchase price of $20.7 million, consisting of 2,525,677 shares of our Series B Convertible Preferred Stock ("Series B Shares") valued at $6.38 per share, the assumption of promissory notes due to Paramount Credit Partners, LLC ("PCP") in the amount of $750,000 and the assumption of Asphelia's obligation to reimburse OvaMed for certain development costs. Of this purchase price $3.8 million was 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 the OvaMed License, we are required to make annual license payments to OvaMed of $250,000, reimburse patent expenses, make potential future payments totaling up to $5.45 million upon the achievement of various milestones related to regulatory events for the first product, and make additional milestone payments upon the achievement of regulatory events relating to subsequent indications. In the event that TSO is commercialized, we will be obligated to pay annual royalties based upon net sales of the product as well as a portion of certain sublicense revenues. We are also required to purchase our clinical and commercial requirements of TSO from OvaMed at pre-determined prices.

In December 2011, we entered into a binding Terms of Agreement with Falk and OvaMed under which we agreed to enter into a collaboration agreement relating to the development of TSO for 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 the Territory. 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 and agreed to pay Falk €5 million (approximately $6.5 million), all of which is currently estimated to be paid by the first half of 2013. We also agreed with Falk to share in certain costs relating to the development of TSO for Crohn's in the United States and Europe.

We acquired an exclusive worldwide license to CNDO–109 in November 2007 from UCLB. In consideration for the license, we paid UCLB initial license fees totaling $0.1 million and are required to make future 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. If CNDO–109 is commercialized, we will be obligated to pay to UCLB annual royalties based upon net sales of the product or a portion of sublicensing revenues.

On June 30, 2011, we completed a private placement of our Series C Convertible Preferred Stock ("Series C Shares") which resulted in net proceeds, after placement agent commissions and offering expenses, of approximately $22.9 million.

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 ("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 ("R&D") Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued R&D 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 R&D expenses as of December 31, 2011 include fees to:

- CROs and other service providers in connection with clinical studies;
- Investigative sites in connection with clinical studies;
- Contract manufacturers in connection with the 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 and 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” 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 employee groups and the expected effect of events that have indications on future exercise activity.
- 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, 2011, 2010, and 2009, stock-based compensation expense was $1.5 million, $2.3 million, and $39,000, respectively. As of December 31, 2011, we had approximately $3.7 million of total unrecognized compensation expense, net of related forfeiture estimates which we expect to recognize over a weighted-average period of approximately 2.2 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 determined by an independent valuation as of that date. All other options previously granted or to be granted in the future were 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 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. 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 ("Series A Shares") at $8.39 per share in 2010 and our 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 the 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 the common stock of the company. 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, valuations, using a theoretical put option model that captures 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.

Results of Operations

General

To date, we have not generated any revenues from operations and, at December 31, 2011, we had an accumulated deficit of $56.6 million primarily as a result of R&D expenses, purchase of in-process research and development and general and administrative ("G&A") expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant revenues.

R&D Expenses

Conducting research and development is central to our business. For the years ended December 31, 2009, 2010 and 2011, R&D expenses were $2.3 million, $8.3 million, $8.6 million, respectively, and such expenses were $24.5 million for the period from inception (June 28, 2006) to December 31, 2011. R&D expenses consist primarily of:

- employee-related expenses, which include salaries and benefits, and rent expense;
- license fees and milestone payments related to in-licensed products and technology;
- expenses incurred under agreements with CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring and manufacturing clinical trial materials; 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 R&D 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, 2011, direct, external development costs incurred for our CNDO–109 product development program were $4.4 million, including $0.4 million, $2.1 million, and $1.9 million respectively, for the years ended December 31, 2009, 2010 and 2011. From inception through December 31, 2011, direct, external development costs incurred for our TSO product development program were $2.9 million, excluding $20.7 million of in-process research and development costs related to our acquisition of the asset in 2011. Our results of operations for the years ended December 31, 2009, 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, 2011, such expenses totaled $5.2 million.

G&A Expenses

G&A 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 R&D. For the years ended December 31, 2009, 2010 and 2011, G&A expenses were $0.3 million, $0.9 million, and $5.8 million, respectively, and such expenses were $7.6 million from inception through December 31, 2011. We anticipate G&A expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded research and development activities;
- an expanding infrastructure and increased professional fees and other costs associated with the Exchange Act, SOX and NASDAQ regulatory requirements and compliance; and
- increased business development activity.

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

R&D 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 relating to 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. Payment of the milestone to OvaMed is due in the fourth quarter of 2012. We expect our R&D expenses to increase in future quarters as we commence our clinical programs for TSO and CNDO–109 and for the contractual payments to Falk of approximately $6.5 million, all of which is currently expected to be paid by the first half of 2013.

G&A expenses increased $4.9 million from the year ended December 31, 2010 to the year ended December 31, 2011, reflecting the 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, $0.5 million in increased stock compensation expense, and $0.4 million increase in consulting and outside services.

In January 2011, we acquired from Asphelia a sublicense and related agreements for TSO and assumed certain liabilities of Asphelia. As consideration for such acquisition, we issued 2,525,677 Series B shares valued at $6.38 per share, assumed the PCP Note 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 to a related party. The total consideration paid in connection with the acquisition of Asphelia's assets, including the assumption of certain liabilities of Asphelia, was $20.7 million, which was recorded as in-process research and development expense in 2011.

In 2011, we incurred $74,000 of interest expense 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 the same period last year was primarily due to higher cash balances.

Warrant expense of $1,407,000 in 2011 is a noncash expense relating to the marking-to-market of the warrants for Series C shares issued to the placement agent for their services in connection with the Series C financing. 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, 2010 and 2009

	For the Year Ended December 31,		Variance	
($ in thousands)	**2010**	**2009**	**$**	**%**
Operating expenses:				
Research and development	$ 8,341	$ 2,270	$ 6,071	267%
General and administrative	900	343	557	162%
Loss from operations	(9,241)	(2,613)	(6,628)	254%
Interest income	61	—	61	NM
Interest expense	(1,535)	(1,053)	(482)	46%
Other income	733	—	733	NM
Net loss	$(9,982)	$(3,666)	$(6,316)	172%

NM—Not meaningful

R&D expenses increased $6.1 million from the year ended December 31, 2009 to the year ended December 31, 2010. This increase was primarily attributable to $2.3 million higher non-cash charges for stock-based compensation, $2.2 million higher salaries and administrative costs associated with increased staffing and related overhead costs, $1.7 million higher expenses related to the technology transfer for CNDO–109 to a GMP environment, and $0.3 million higher costs relating to our two discontinued product development programs.

G&A expenses increased $0.6 million from the year ended December 31, 2009 to the year ended December 31, 2010. This increase is primarily attributable to higher legal, accounting and other professional expenses and increased personnel-related costs due to increased staffing to support our product development programs and establish and infrastructure to support growth.

Interest income was $61,000 for the year ended December 31, 2010. There was minimal interest income for the year ended December 31, 2009. The interest income in 2010 was primarily attributable to cash balances resulting from the proceeds of our Series A shares issued in April 2010.

Other income of $0.7 million for the year ended December 31, 2010 reflects the government grant received by us under the Therapeutic Discovery Project. This income will not be recurring.

Interest expense, net includes interest on our senior notes, related party notes and the amortization of costs associated with charges for the issuance of debt. For the year ended December 31, 2010 total interest expense, was $1.5 million, compared with $1.1 million for the year ended December 31, 2009. $0.8 million in 2010 related to the amortization of the embedded conversion feature of the senior convertible and related party notes, partially offset by reduced interest expense on this debt that converted to Series A Shares in April 2010.

Liquidity and Capital Resources

To date, we have funded our operations through the sale of debt and equity securities aggregating $52.1 million of net proceeds. At December 31, 2011, we had cash and cash equivalents of $23.2 million. On June 30, 2011, we completed a private placement of our Series C Shares which resulted in net proceeds, after placement agent commissions and offering expenses, of approximately $22.9 million.

We expect to incur substantial expenditures in the foreseeable future for the research, development and potential commercialization of our product candidates. We will require additional financing to develop, prepare regulatory filings and obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt. We believe that our current cash and cash equivalents are sufficient to fund operations into the fourth quarter of 2012 based on our current business plan. Our current financial condition raises substantial doubt about our ability to continue as a going concern. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We will seek funds through 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 will be required to delay, curtail or eliminate one or more of our research and development programs.

As of December 31, 2010, all notes and other debt was either repaid or converted into our Series A Shares. At December 31, 2011, we had outstanding $750,000 of promissory notes due to PCP which we assumed from Asphelia. These notes are due in December 2013 or earlier in the event of a merger transaction.

On November 15, 2011, our resale registration statement on Form S-1 became effective. Upon effectiveness, all of our then outstanding Series A Shares, Series B Shares and Series C Shares automatically converted into shares of our common stock on a one-to-one basis, resulting in an 11,496,186 share increase in our outstanding common stock and an increase in additional paid in capital of $66,993,000. After the conversion, we had 18,524,185 shares of common stock outstanding. Additionally, upon effectiveness of the Form S-1, our 461,263 outstanding warrants for Series C Shares became exercisable for common stock. As of November 15, 2011, we determined the fair value of these warrants to be $2,693,000, a $1,407,000 increase from the original valuation of $1,286,000 at June 30, 2011, and during the year ended December 31, 2011, recorded this increase in warrant liability as a noncash charge. The final warrant liability of $2,693,000 was reclassified to additional paid in capital.

Cash Flows for the Three Years Ended December 31, 2011, 2010 and 2009

($ in thousands)	For the Year Ended December 31, 2011	2010	2009
Statement of Cash Flows Data:			
Total cash provided by (used in):			
Operating activities	$(10,952)	$ (5,677)	$(2,351)
Investing activities	(3,843)	(13)	(2)
Financing activities	23,093	19,042	3,856
Increase in cash and cash equivalents	$ 8,298	$13,352	$ 1,503

Operating Activities

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 $26.3 million, included $1.4 million related to the increase to the fair value of the Series C warrant liability and $1.6 million related to the increase in accounts payable and accrued expenses, offset by $20.7 million of noncash expense for in-process research and development expense related to the Asphelia asset purchase, a $0.9 million decrease in stock-based compensation and a $0.9 million decrease in the change in fair value of a warrant-embedded conversion feature.

Cash used in operating activities increased $3.3 million from the year ended December 31, 2009 to the year ended December 31, 2010 primarily due to increased operating expenses partially offset by the $0.7 million government grant received in 2010.

Investing Activities

Net cash used in investing activities was $3.8 million in 2011 and consisted solely of cash payments related to the Asphelia asset purchase.

Cash used in investing activities for the years ended December 31, 2010 and 2009 was not significant.

Financing Activities

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 issuance of the Series C Shares and $193,000 from exercise of employee stock options.

Cash provided by financing activities increased $15.2 million from the year ended December 31, 2009 to the year ended December 31, 2010 primarily due to the issuance of our Series A Shares which resulted in net proceeds of $19.4 million in 2010, while the primary source of cash from financing activities in 2009 was $3.9 million from net debt proceeds.

Contingent Contractual Payments

Based on our development plans and license agreements in effect as of December 31, 2011, we have committed to make potential future milestone payments to our licensors upon achievement of certain development or regulatory milestones. Under the OvaMed License for TSO, the milestone payments aggregate approximately $5.45 million, including $1.5 million relating to the achievement of the milestone for the filing of an IND for TSO, for the first indication and $2.0 million for each subsequent indication. Under the UCLB license for CNDO–109, the milestone payments aggregate approximately $22 million for the first three indications. We incurred a milestone-related charge of $1.5 million in the three month period ended December 31, 2011 relating to the filing of an IND for our first indication for TSO. Payment for this milestone to OvaMed is due in the fourth quarter of 2012. In addition, as a result of the Collaboration Agreement entered into in March 2012, we have committed to pay Falk €5 million (approximately $6.5 million based on exchange rates effective on December 31, 2011), all of which is estimated to be paid by the first half of 2013. Additionally, under employment agreements with certain of our executive officers, such officers are entitled to cash bonuses based on our common stock satisfying certain market capitalization, trading volume and other criteria.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Quantitative and Qualitative Disclosures about Market Risks

We held no marketable securities at December 31, 2010 and 2011. Our existing debt is at a fixed rate and we currently do not have exposure to foreign currency fluctuations.

Net Operating Loss Tax Carry-Forwards

As of December 31, 2011, we had net federal operating loss carryforwards of approximately $27.9 million to offset future federal income taxes which expire beginning in 2026. 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, 2010 and 2011, 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 fully 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 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 financial statements required to be filed with this Annual Report begin on page F-1.

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

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, 2011, 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 generally accepted accounting principles, 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 cannot provide absolute assurance of achieving financial reporting objectives because of its 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. Management is responsible for establishing and maintaining adequate internal control over financial reporting for our company.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness, as of the end of the period covered by this report, of our disclosure controls and procedures, as such term is defined in Exchange Act Rule 13a-15(e). Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective.

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Controls over Financial Reporting.

There has been no change in our internal control over financial reporting during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Certain information required by Part III is omitted from this Annual Report since we intend to file our definitive Proxy Statement for our next Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended ("2012 Proxy Statement"), within 120 days of the end of the fiscal year covered by this report, and certain information to be included in the 2012 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our 2012 Proxy Statement under the captions Election of Directors and is incorporated herein by reference—Nominees of the Board of Directors; Election of Directors—Section 16(a) Beneficial Ownership Compliance; Election of Directors—Board Operations, and Election of Directors—Board Committees—Audit Committee—and Election of Directors—Board Committees—Nominating and Corporate Governance Committee.

Item 11. Executive Compensation.

The information required by this item will be contained in our 2012 Proxy Statement to be set forth in the 2012 Proxy Statement under the captions Election of Directors—Executive Compensation and is incorporated herein by reference.

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

The information required by this item will be contained in our 2012 Proxy Statement under the caption Security Ownership of Certain Beneficial Owners and Management and is incorporated herein by reference.

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

The information required by this item will be contained in our 2012 Proxy Statement under the caption Election of Directors and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be contained in our 2012 Proxy Statement under the captions Ratification of the Appointment of Independent Accountants and is incorporated herein by reference.

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 to Amended and Restated Certificate of Incorporation. (1)
3.3	Certificate of Designation, Preferences and Rights of the Series B Convertible Preferred Stock. (1)
3.4	Certificate of Designation, Preferences and Rights of the Series C Convertible Preferred Stock. (1)
3.6	Amended and Restated Bylaws of the Registrant. (1)
4.1	Form of Common Stock Certificate. (1)

Exhibit Number	Description
4.2	Form of Series A Convertible Preferred Stock Certificate. (1)
4.3	Form of Series B Convertible Preferred Stock Certificate. (1)
4.4	Form of Series C Convertible Preferred Stock Certificate. (1)
4.5	Form of Warrant to Purchase Common Stock issued by the Registrant in connection with the 2008 bridge financing. (1)
4.6	Form of Warrant to Purchase Common Stock issued by the Registrant in connection with the 2009 bridge financing. (1)
4.7	Form of Warrant to Purchase Common Stock issued by the Registrant in connection with the Series A financing. (1)
4.8	Form of Warrant to Purchase Series C Convertible Preferred Stock issued by the Registrant in connection with the 2011 Series C financing. (1)
4.9	Form of Consultant/Agent Warrant to Purchase Common Stock. (1)
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 the Registrant and Manchester Securities Corp. (1)
10.8*	2007 Stock Incentive Plan. (1)
10.9*	Form of Stock Option Award Agreement. (1)
10.10†	Exclusive Sublicense Agreement, dated December 12, 2005, by and between OvaMed GmbH and Collingwood Pharmaceuticals, Inc. (1)
10.11†	Manufacturing and Supply Agreement, dated March 29, 2006, by and among OvaMed GmbH and Collingwood Pharmaceuticals, Inc. (1)
10.12†	Licence Agreement, dated November 5, 2007, by and 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, dated September 30, 2009, by and between the Registrant and UCL Business PLC. (1)

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Exhibit Number	Description
10.15†	Master Contract Services Agreement, dated 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 Pharmaceuticals, 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 January 7, 2011, by and between the Registrant and Asphelia Pharmaceuticals, Inc. (1)
10.19*	Employment Agreement, dated March 21, 2011, by and among Registrant and Bobby W. Sandage, Jr., Ph.D. (1)
10.20*	Employment Agreement, dated April 1, 2011, by and among the Registrant and Glenn L. Cooper. M.D. (1)
10.21*	Employment Agreement, dated 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, dated 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, dated March 12, 2008, by and between the Registrant and BioReliance Corporation, as amended. (1)
10.28	Consulting Agreements between the Registrant and each of Dr. Mark Lowdell 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, dated September 26, 2011, by and between the Registrant and Noah D. Beerman. (2)
10.31	Consulting Agreement, dated September 27, 2011, by and between the Registrant and Joel Weinstock, M.D. (3)
10.32	Terms of Agreement among the Registrant, OvaMed and Falk effective as of December 22, 2011. (4)
10.33*	Amendment to Employment Agreement between the Registrant and Bobby W. Sandage, Jr., Ph.D. effective as of December 19, 2011. (4)
10.34	Side Agreement among the Registrant, UIRF and OvaMed effective as of November 15, 2011. (4)

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Exhibit Number	Description
10.35*	Employment Agreement, dated February 21, 2012, by and between the Registrant and Lucy Lu. (5)
10.36††	Collaboration Agreement among the Registrant, Dr. Falk Pharma GmbH and OvaMed GmbH dated March 20, 2012 (7)
14.1	Code of Ethics of Coronado Biosciences, Inc. applicable to Directors, Officers and Employees. (6)
21.1	Subsidiaries of the Registrant. (1)
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 and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data Files

† 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 an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on September 26, 2011.
(3) 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.
(4) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on December 22, 2011.
(5) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on February 23, 2012.
(6) 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.
(7) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on March 23, 2012.

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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.
(a development stage enterprise)

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, 2011 and December 31, 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 and, cumulatively, for the period from June 28, 2006 (date of inception) to December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations since inception and will require additional financing to fund future operations. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP
Boston, Massachusetts
March 29, 2012

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

	December 31, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 23,160	$ 14,862
Prepaid and other current assets	215	55
Total current assets	23,375	14,917
Computer equipment, net of accumulated depreciation	—	22
Total Assets	$ 23,375	$ 14,939
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 575	$ 476
Accounts payable—related party	—	46
PCP interest payable—related party	19	—
Accrued expenses	2,899	1,037
Total current liabilities	3,493	1,559
PCP notes payable—related party	750	—
Total Liabilities	4,243	1,559
Commitments and Contingencies (Note 6)		
Convertible Preferred Stock, $.001 par value, 461,263 Series C Shares authorized, 0 shares issued and outstanding as of December 31, 2011; 10,000,000 shares authorized, 4,357,885 Series A Shares issued and outstanding as of December 31, 2010, net of issuance costs (liquidation value of $54,844 as of December 31, 2010)	—	29,277
Stockholders' Equity (Deficit):		
Common Stock, $.001 par value, 50,000,000 shares authorized, 18,604,245 shares issued and outstanding as of December 31, 2011; 4,791,102 shares issued and outstanding as of December 31, 2010;	19	5
Additional paid-in capital	75,687	4,312
Deficit accumulated during development stage	(56,574)	(20,214)
Total Stockholders' Equity (Deficit)	19,132	(15,897)
Total Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)	$ 23,375	$ 14,939

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,
	2011	2010	2009	2011
Operating expenses:				
Research and development	$ 8,583	$ 8,341	$ 2,270	$ 24,542
General and administrative	5,755	900	343	7,614
In-process research and development	20,706	—	—	20,706
Loss from operations	(35,044)	(9,241)	(2,613)	(52,862)
Interest income	165	61	—	244
Interest expense	(74)	(1,535)	(1,053)	(3,282)
Other income	—	733	—	733
Warrant expense	(1,407)	—	—	(1,407)
Net loss	(36,360)	(9,982)	(3,666)	(56,574)
Common Stock dividend to Series A Convertible Preferred Stockholders	(5,861)	—	—	(5,861)
Net loss attributed to Common Stockholders	$ (42,221)	$ (9,982)	$ (3,666)	$ (62,435)
Basic and diluted net loss per common share	$ (5.51)	$ (2.24)	$ (1.01)	
Weighted average common shares outstanding—basic and diluted	7,662,984	4,453,786	3,612,769	

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

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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, 2011
($ in thousands except for share amounts)

	Preferred Stock		Common Stock		Additional paid-in capital	Equity (Deficit) accumulated during development stage	Total Stockholders' (deficit)
	Shares	Amount	Shares	Amount			
Balances at June 28, 2006 (Date of Inception)	—	$ —	—	$ —	$ —	$ —	$ —
Net loss	—	—	—	—	—	(123)	(123)
Balances at December 31, 2006	—	—	—	—	—	(123)	(123)
Issuance of Common Stock to founders	—	—	2,125,096	2	—	—	2
Issuance of restricted Common Stock to non-employees	—	—	2,180,000	2	—	—	2
Issuance of restricted Common Stock to employees	—	—	457,170	1	—	—	1
Stock-based compensation expense	—	—	—	—	13	—	13
Net loss	—	—	—	—		(2,645)	(2,645)
Balances at December 31, 2007	—	—	4,762,266	5	13	(2,768)	(2,750)
Stock-based compensation expense	—	—	—	—	25	—	25
Contribution of services by stockholder	—	—	—	—	20	—	20
Net loss	—	—	—	—		(3,798)	(3,798)
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)
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							

Warrant liability	—	—	138,040	—1	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

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,
	2011	2010	2009	2011
Cash flows from operating activities:				
Net loss	$(36,360)	$ (9,982)	$(3,666)	$ (56,574)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	1,469	2,329	39	3,874
Acquired in-process research and development	20,706	—	—	20,706
Noncash interest	—	236	493	1,031
Noncash interest—related parties	—	34	101	286
Contribution of services by stockholder	30	40	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
Amortization of deferred financing costs	—	157	415	737
Depreciation expense	22	5	5	41
Changes in operating assets and liabilities:				
Other current assets	(160)	(51)	203	(215)
Interest payable—related parties	19	(38)	38	19
Accounts payable and accrued expenses-related parties	(46)	46	—	—
Accounts payable and accrued expenses	1,961	361	(19)	3,474
Net cash used in operating activities	(10,952)	(5,677)	(2,351)	(23,898)
Cash flows from investing activities:				
Purchase of computer equipment	—	(13)	(2)	(41)
Purchase of in-process research and development	(3,843)	—	—	(3,843)
Net cash used in investing activities	(3,843)	(13)	(2)	(3,884)
Cash flows from financing activities:				
Proceeds from PCP notes payable—related party	—	—	570	570
Payment of PCP notes payable—related party	—	(570)	—	(570)
Proceeds from notes payable—related parties	—	302	90	2,221
Proceeds from issuance of Convertible Preferred Stock Series A	—	21,681	—	21,681
Payment of costs related to the issuance of Convertible Preferred Stock Series A	—	(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	—	—	40	80
Payment of line of credit	—	(80)	—	(80)
Proceeds from Senior Convertible Notes	—	—	3,500	7,570
Payment of debt issue costs	—	—	(344)	(737)
Payment of notes payable—related parties	—	—	—	(600)
Proceeds from issuance of Common Stock	193	—	—	198
Net cash provided by financing activities	23,093	19,042	3,856	50,942
Increase in cash and cash equivalents	8,298	13,352	1,503	23,160
Cash and cash equivalents—beginning of period	14,862	1,510	7	—
Cash and cash equivalents—end of period	$ 23,160	$14,862	$ 1,510	$ 23,160
Supplemental disclosure of cash flow information:				
Cash paid for interest	$ 53	$ 81	$ 7	$ 141

	For the Year Ended December 31,			Period from June 28, 2006 (Date of Inception) to December 31,
	2011	2010	2009	2011
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

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

Coronado Biosciences, Inc. and Subsidiary

(A development stage enterprise)
Notes to the 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 $56.6 million as of December 31, 2011. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates. To date, the Company's operations have been funded primarily by issuing equity securities 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 12). All 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 12). On November 15, 2011, the Company's Resale Registration Statement on Form S-1 was declared effective resulting in the conversion of 4,357,855 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.

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 in the Series C Shares financing (see Note 12) are sufficient to sustain operations into the fourth quarter of 2012 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 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. These circumstances raise substantial doubt about the Company's ability to continue as a going concern.

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 convertible preferred stock ("Preferred Stock"), 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 entire business is managed by a single management team that reports to the chief executive officer. 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 completely dependent on third party manufacturers for product supply. In particular the Company relies and expects to continue to rely exclusively on OvaMed GmBH ("OvaMed") to supply it with its requirements of Trichusirus suis ova or CNDO–201 ("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 clinical trials by third parties, including Dr. Falk Pharma GmbH ("Falk"). Similarly, the Company relies on BioReliance Corporation ("BioReliance") and Progenitor Cell Therapy LLC ("PCT") for its CNDO–109 requirements and its CNDO–109 clinical program would be adversely affected by a significant interruption in the supply of this product.

Cash and Cash Equivalents and Concentration of Credit Risk

Cash and cash equivalents consist of cash. The Company maintains all cash in one institution in the United States. Balances at this institution may exceed Federal Deposit Insurance Corporation insured limits. Investments are made in accordance with the Company's policies.

Computer Equipment

Computer equipment is stated at cost less accumulated depreciation. The estimated useful life of computer equipment is five years.

Deferred Financing Costs

Financing costs incurred in connection with the Paramount Credit Partners, LLC ("PCP") note (the "PCP Note") and related party notes were capitalized at the inception of the notes and amortized over the appropriate expected life based on the terms of the respective note. Financing costs incurred in connection with the Company's Series A Share and Series C Share offerings were recorded as a reduction to their carrying value.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the asset. There have been no such impairments of long-lived assets to date.

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.

Prior to the commencement of public trading of the Company's Common Stock on November 17, 2011, determining the appropriate fair value of stock-based awards required the use of subjective assumptions. In the absence of a public trading market for its Common Stock, the Company performed periodic contemporaneous assessments of the valuation of the Company's Common Stock. The Company considered numerous objective and subjective factors, including but not limited to the following factors:

- Arm's length private transactions involving the Company's Preferred Stock;
- Financial and operating performance;
- Market conditions;
- Developmental milestones achieved;
- Business risks; and
- Management and board experience.

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. As of November 17, 2011, the Company utilizes its public trading price in determining the fair value of its stock-based awards.

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 September 2011, the Financial Accounting Standards Board ("FASB") issued amended accounting guidance for goodwill in order to simplify testing for impairment. The amendments are effective for interim and annual impairment test for fiscal years after December 31, 2011. Adoption is not expected to have a material impact on the Company's consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05 *Presentation of Comprehensive Income* which requires changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate statements. The amendment is effective for periods beginning after December 15, 2011, shall be applied retrospectively and is not expected to have a material impact on the Company's consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04 *Amendments to achieve common fair value measurement and disclosure requirements in US GAAP and IFRS*. This amendment changes wording used to describe many of the requirements in US GAAP for measuring fair value and disclosing information at fair value. The amendment is effective for periods beginning after December 15, 2011. The Company is currently evaluating the disclosure requirements, which are not expected to have a material impact on the Company's financial statements.

3. Net Loss Per Common Share

The Company calculates earnings (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 shares and participating securities based on their respective rights to receive dividends. Holders of the Series A Shares were entitled to and did receive in May 2011, a Common Stock dividend equal to 50% of Series A Shares held. Additionally, 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 only included in the calculation of diluted net loss per share when the effect is dilutive. As of November 15, 2011, the Company issued 11,496,186 shares of Common Stock as a result of the conversion of its Series A, Series B and Series C Shares. For the year ended December 31, 2011, a weighted percentage of this Common Stock was included in the common shares outstanding.

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)	2011	2010	2009
Historical net loss per share:			
Numerator			
Net loss	$ (36,360)	$ (9,982)	$ (3,666)
Common Stock dividend to Series A Preferred Stockholders	(5,861)	—	—
Net loss attributed to Common Stockholders	$ (42,221)	$ (9,982)	$ (3,666)
Denominator			
Weighted-average common shares outstanding—Denominator for basic and diluted net loss per share	7,662,984	4,453,786	3,612,769
Basic and diluted net loss per share attributed to common stockholders	$ (5.51)	$ (2.24)	$ (1.01)

The Company's potential dilutive securities which include convertible debt, 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,		
	2011	2010	2009
Series A Shares	3,796,733	2,617,243	—
Series B Shares	2,158,935	—	—
Series C Shares	1,966,635	—	—
Unvested restricted Common Stock	—	322,900	1,146,980
Warrants to purchase Common Stock	533,249	261,861	87,002
Warrants to purchase Series C Shares	256,059	—	—
Options to purchase Common Stock	1,479,291	296,112	—
	10,190,902	3,498,116	1,233,982

4. Computer Equipment

Computer equipment consisted of the following:

	As of December 31,	
($ in thousands)	2011	2010
Computer equipment	$ 41	$ 41
Less: Accumulated depreciation	(41)	(19)
Computer equipment, net	$ —	$ 22

Depreciation expense for the years ended December 31, 2011, 2010, and 2009 and the period from inception to December 31, 2011 was $22,000, $5,000, $5,000 and $41,000, respectively, and was recorded as general and administrative expense in the consolidated statement of operations.

5. Accrued Liabilities

Accrued expenses consisted of the following:

	As of December 31,	
($ in thousands)	2011	2010
Salaries, bonuses and related benefits	$ 493	$ 553
Professional fees	215	309
Research and development expenses	653	143
Accrued milestone	1,500	—
Other	38	32
Total accrued expenses	$2,899	$1,037

6. Commitments and Contingencies

Operating Lease Obligations

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

The Company recognizes rent expense on a straight-line basis over the non-cancellable lease term. Rent expense for the years ended December 31, 2011, 2010 and 2009 and the period from inception to December 31, 2011 was $165,000, $97,000, $2,000 and $264,000, respectively. The Company did not have any leased facilities prior to 2009.

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.

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. During the years ended December 31, 2011, 2010 and 2009, no claims have been brought by or against the Company and its subsidiary.

7. 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 is payable 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.

The OvaMed Supply Agreement currently expires in March 2013 but will automatically renew for successive one-year periods, unless the Company gives 12 months prior notice of its election not to renew. The OvaMed Supply Agreement is subject to early termination by either party under certain customary conditions of breach and by the Company in the event of specified failures to supply or regulatory or safety failures.

8. 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. In 2011 the Company paid a matching contribution of $77,000. No match was paid in prior years.

9. 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.

During 2011, the Company valued its liability related to warrants issued pursuant to an offering of Series C Shares using the Black-Scholes option pricing model (see Note 13) with unobservable inputs and was therefore considered a Level 3 fair value measurement.

Some of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate fair value due to their liquid or short-term nature, such as cash and cash equivalents, prepaid expenses, other current assets, other long-term assets, accounts payable, accrued expenses and other current liabilities. The carrying amount of the Company's debt obligations approximate fair value based on the short-term duration and interest rates available on similar borrowings.

10. Related Party Transactions

Services Agreement

In November 2006, the Company entered into a consulting contract with Paramount BioSciences, LLC ("PBS") an affiliate of a principal stockholder and director of the Company (the "Principal Stockholder/Director"), under which PBS provided certain drug development, professional, administrative and accounting services. Total fees for the period from inception to December 31, 2008 were $550,000. Since December 31, 2008 no fees have been incurred.

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 11). For the services rendered, PBC received cash payments for commissions and reimbursement of expenses as well as warrants to purchase Common Stock (see Notes 11 and 13).

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, 2011. In addition, certain trusts established for the benefit of family members of the Principal Stockholder/Director beneficially owned an aggregate of approximately 7.9% of the Company's outstanding capital stock as of December 31, 2011.

National Securities Corporation, placement agent for our Series C Share financing (see Note 12), is a related party to the Principal Stockholder/Director.

A non-employee director and one of the Company's previous officers are or were employees of PBS.

11. Debt

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. Certain events include either the consummation of an equity financing in which gross proceeds to the Company equal or exceed 250% of the outstanding principal amount, an initial public offering or a sale of the Company. 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 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 either the consummation of an equity financing in which gross proceeds to the Company equal or exceed 250% of the outstanding principal amount or a reverse merger or sale of the Company. 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 13). 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. This amount was not material.

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 7), the Company assumed a $750,000 10% promissory note issued to PCP by Asphelia. All unpaid principal and accrued interest outstanding under the PCP Notes was payable on the earlier of (i) December 31, 2013, or (ii) the consummation of a merger, exchange or other transaction (or series of related transactions), other than in connection with the consummation of an equity financing (or a series of equity financings) in which the aggregate consideration payable to the Company or its stockholders is greater or equal to $10 million. The PCP Note is classified as a long-term liability at December 31, 2011 on the consolidated balance sheet.

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 $0.7 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. For the years ended December 31, 2010, 2009 and the period from inception to December 31, 2011, amortization of deferred financing costs was $0.2 million, $0.4 million, and $0.7 million, respectively.

Line of Credit Facility

In December 2008, the Company, PBS and certain affiliates of PBS jointly entered into a revolving line of credit agreement with an unrelated financial institution. The line of credit was secured by collateral pledged by PBS. The line of credit was repaid in full and closed during 2010.

Interest expense for all debt is as follows:

	For the Year Ended December 31,			Period from June 28, 2006 (Date of Inception) to
($ in thousands)	2011	2010	2009	December 31, 2011
Interest expense	$—	$ 237	$ 493	$ 1,032
Interest expense—related parties	74	76	145	448
Amortization of embedded conversion feature	—	831	—	831
Change in fair value of Common Stock warrant liability	—	234	—	234
Amortization of deferred financing fees	—	157	415	737
Total interest expense	$ 74	$ 1,535	$ 1,053	$ 3,282

12. 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, 2011 and 2010, there were 0 Series A Shares and 4,357,885 Series A Shares outstanding, respectively.

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) if the Company's capital stock becomes publicly traded, then the date upon which such capital stock has a publicly traded value of $12.59 or more per share, as adjusted for any stock splits, stock exchanges, recapitalizations, dividends and the like (such date, the "Valuation Milestone Date"). The Valuation Milestone Date shall be deemed to have occurred: (i) on the date which the Company's capital stock first becomes publicly traded, if such capital stock has an initial quoted value greater than or equal to $12.59 per share, or (ii) the date that is the twentieth (20th) consecutive or non-consecutive trading day where the volume-weighted average price for the Company's capital stock as reported by Bloomberg Financial L.P. is greater than or equal to $12.59 per share, in each case as adjusted for any stock splits, stock exchanges, recapitalizations and dividends as determined by the Company's board of directors in its reasonable discretion.

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 were 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.

The Series A Shares were redeemable upon a liquidation event, including liquidation, winding up, and dissolution of the Company. Additionally, the holders would be entitled to receive cash in the event of an acquisition, including a merger or consolidation or asset transfer. Certain of these events would not be considered solely within the Company's control. As a result, outstanding Series A Shares have been classified as mezzanine equity in the consolidated balance sheet at December 31, 2011.

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 were 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, 2011, there were 461,263 Series C Shares authorized and reserved for issuance of Common Stock 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, 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 14). 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 14). PBS provides 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 31, 2011, 2010, 2009, and for the period from inception to December 31, 2011 was $0.0 million, $2.0 million, $39,000 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 and no restricted Common Stock issuances were made for the year ended December 31, 2011.

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).

13. Warrants to Purchase Common Stock

Debt Placement Agent Warrants

In connection with the issuance of the Senior Convertible Notes (see Note 11), 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.

The fair value of the warrants was measured on the dates of issuance using a binomial option pricing model. The Company determined that the warrants would not be considered indexed to the Company's stock, and therefore, the warrants were initially recorded as a derivative liability in the consolidated balance sheets. For each subsequent period through April 26, 2010, the change in the fair value of the warrants was recognized as interest expense in the consolidated statements of operations. The fair value of the warrants prior to 2010 was not material to the consolidated financial statements.

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. The fair value of the warrants related to the 2008 Senior Convertible Notes was determined using an option pricing model assuming a 95.4% volatility, a 1.7% risk-free rate of interest, a term of 4.8 years and an estimated per share fair value of the Company's Common Stock of $3.45. The fair value of the warrants related to the 2009 Senior Convertible Notes was determined using an option pricing model assuming a 93.4% volatility, a 2.9% risk-free rate of interest, a term of 6.2 years and an estimated per share fair value of the Company's Common Stock of $3.45. In April 2010, the total fair value $0.2 million of the warrants was reclassified from a liability to additional paid-in capital in the consolidated balance sheets.

The initial warrant fair values were recorded as debt issuance costs and amortized over the estimated life of the respective debt (see Note 11).

PCP Warrants

In connection with the issuance of the PCP Notes in 2009 (see Note 11), 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. The Company determined that the warrants would not be considered indexed to the Company's stock, and therefore, the warrants were initially recorded as a derivative liability in the consolidated balance sheet. For each subsequent period through April 26, 2010, the change in the fair value of the warrants was recognized as interest expense in the consolidated statement of operations. The fair value of the warrants prior to 2010 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. The fair value of the warrants was determined using an option pricing model assuming a 98.3% volatility, an average 2.1% risk-free rate of interest, a term of 3.8 – 4.2 years and an estimated per share fair value of the Company's Common Stock of $3.45. The fair value on April 26, 2010 totaling $47,000 was reclassified from a liability to additional paid-in capital in the consolidated balance sheets.

Preferred Stock Placement Warrants

In connection with the issuance of the Company's Series A Shares (see Note 12), the Company issued seven-year warrants to purchase an aggregate of 258,418 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 12) 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 no future service was required.

In February 2011, the Company issued 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.

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.

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.

14. 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 3,470,610 were granted, net of cancellations, and 2,529,930 shares were available for issuance as of December 31, 2011.

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 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 assumptions were used:

Stock option plans	2011	2010
Exercise price	$ 1.37–$6.00	$ 1.37
Expected stock price volatility	87.5%–92.8%	92.7%–95.2%
Risk free rate of interest	1.17%–2.56%	1.52%–2.50%
Expected life of options	6years–10years	6years–10years

The following table summarizes the stock-based compensation expense from stock option and restricted Common Stock awards and warrants for the years ended December 31, 2011, 2010 and 2009, and from the period June 28, 2006 (Date of Inception) to date:

($ in thousands)	2011	2010	2009	Period from June 28, 2006 (Date of Inception) to December 31, 2011
Employee awards	$ 520	$ 215	$—	$ 735
Non-employee awards	662	2,114	39	2,852
Non-employee warrants	287	—	—	287
Total compensation expense	$1,469	$2,329	$ 39	$ 3,874

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, 2010	1,228,190	$ 1.37	$ 466	9.8
Options granted	1,165,000	$ 2.65		
Options exercised	(138,040)	$ 1.40		
Options forfeited	(441,080)	$ 1.44		
Options expired	—	—		
Outstanding at December 31, 2011	1,814,070	$ 2.17	$ 7,852	9.2
Options vested and expected to vest	1,748,763	$ 2.17	$ 7,569	9.2
Options vested and exercisable	254,690	$ 1.43	$ 1,291	9.2

As of December 31, 2011, the Company had unrecognized stock-based compensation expense related to all unvested stock options of $3.7 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.2 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 commences February 1, 2012 and will end 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. As of December 31, 2011 all the shares were available for issuance under the plan. The ESPP is compensatory and will result in stock-based compensation expense. The ESPP is subject to shareholder approval.

15. License Agreements

TSO

In addition to the OvaMed Agreements acquired pursuant to the Asphelia Asset Purchase (see Note 7), the Company also entered into the following agreements relating to TSO:

Terms of Agreement and Collaboration Agreement with OvaMed and Falk

In December 2011, the Company entered into a binding Terms of Agreement with Falk and OvaMed to agree to enter into a collaboration agreement relating to the development of TSO for Crohn's disease (the "Collaboration Agreement"). In March 2012, the parties entered into the Collaboration Agreement under which 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.

In addition, the Company agreed to pay Falk a total of €5 million (approximately $6.5 million) after receipt of certain preclinical and clinical data, all of which is currently expected to be paid by the first half of 2013, 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 Coronado, Falk and OvaMed representatives will oversee the development program, under which Coronado 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 Coronado 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. 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.

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.

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 in the accompanying consolidated financial statements and has established a full valuation allowance of $20.6 million against its deferred tax assets.

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

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

	As of December 31,	
($ in thousands)	**2011**	**2010**
Deferred tax assets:		
Net operating loss carryforwards	$ 10,729	$ 6,308
Amortization of up-front fees	43	47
Amortization of in-process R&D	7,778	—
Stock compensation	531	60
Accruals and reserves	846	234
Tax credits	700	—
Total deferred tax assets	20,627	6,649
Valuation allowance	(20,627)	(6,649)
Net deferred tax assets	$ —	$ —

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

	For the Year Ended December 31,		
	2011	2010	2009
Percentage of pre-tax income			
U.S. federal statutory income tax rate	35%	35%	35%
State taxes, net of federal benefit	5%	—	—
Debt modification costs	—	(3)%	0%
Credits	2%	—	—
Other (1)	(4)%	(1)%	0%
Change in valuation allowance	(38)%	(31)%	(35)%
Effective income tax rate	0%	0%	0%

(1) – Other consists of: nondeductible items (2%), 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. Due to the Company's recent history of operating losses, management believes that the deferred tax assets arising from the above-mentioned future tax benefits are currently uncertain with respect to realization and, accordingly, has provided a full valuation allowance.

As of December 31, 2011, the Company has federal net operating loss carryforwards and research and development tax credit carryforwards of approximately $27.9 million and $0.7 million, respectively, which expire beginning in 2026 and 2028, respectively. As of December 31, 2011, the Company has state net operating loss carryforwards of approximately $20.0 million, which expires beginning in 2021 to 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, 2011, 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, 2011. The tax years 2006 through 2011 remain open to examination by one or more major taxing jurisdictions to which the Company is subject.

17. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for fiscal years 2011 and 2010. 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
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)
2010				
Operating expenses	$ (2,302)	$(2,468)	$(2,083)	$(2,389)
Other income/(expense)	$ (1,114)	$ (351)	$ (37)	$ 761
Net loss	$ (3,416)	$(2,819)	$(2,120)	$(1,628)
Basic and diluted net loss per common share	$ (0.86)	$ (0.66)	$ (0.44)	$ (0.34)

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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/ Bobby W. Sandage, Jr.
Name: Bobby W. Sandage, Jr., Ph.D.
Title: Chief Executive Officer and President
(principal executive officer)

March 29, 2012

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/ Glenn L. Cooper Glenn L. Cooper, M.D.	Executive Chairman of the Board of Directors	March 29, 2012
/s/ Bobby W. Sandage, Jr. Bobby W. Sandage, Jr., Ph.D	Chief Executive Officer, President and Director (principal executive officer)	March 29, 2012
/s/ Dale Ritter Dale Ritter	Senior Vice President, Finance, Chief Accounting Officer (principal accounting officer)	March 29, 2012
/s/ Lucy Lu Lucy Lu, M.D.	Chief Financial Officer (principal financial officer)	March 29, 2012
/s/ Eric K. Rowinsky Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	March 29, 2012
/s/ David J. Barrett David J. Barrett	Director	March 29, 2012
/s/ Jimmie Harvey, Jr. Jimmie Harvey, Jr., M.D.	Director	March 29, 2012
/s/ J. Jay Lobell J. Jay Lobell	Director	March 29, 2012
/s/ Michael W. Rogers Michael W. Rogers	Director	March 29, 2012
/s/ Lindsay A. Rosenwald Lindsay A. Rosenwald, M.D.	Director	March 29, 2012

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Rule 13A-14(A)/15D-14(A)
of the Securities Exchange Act of 1934

I, Bobby W. Sandage, Jr., Ph.D., Chief Executive Officer (Principal Executive Officer), certify that:

(1) I have reviewed this Annual Report on Form 10-K of Coronado Biosciences, Inc. (the "Registrant");

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

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

(4) The registrant's other certifying officers 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)) 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. evaluated the effectiveness of 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

c. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's fourth fiscal quarter 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 controls over financial reporting.

By: /s/ Bobby W. Sandage, Jr.
Bobby W. Sandage, Jr., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

March 29, 2012

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Rule 13A-14(A)/15D-14(A)
of the Securities Exchange Act of 1934

I, Lucy Lu, M.D. Chief Financial Officer, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Coronado Biosciences, Inc. (the "Registrant");

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

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

(4) The registrant's other certifying officers 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)) 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. evaluated the effectiveness of 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

c. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's fourth fiscal quarter 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 controls over financial reporting.

By: /s/ Lucy Lu

Lucy Lu, M.D.
Chief Financial Officer
(Principal Financial Officer)

March 29, 2012

Exhibit 32.1

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350 AND EXCHANGE ACT RULES 13a-14(b) AND 15d-14(b)

(Section 906 of the Sarbanes-Oxley Act of 2002)

In connection with the Annual Report of Coronado Biosciences, Inc. on Form 10-K for the fiscal year ended December 31, 2011, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned does 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 the best of his or her knowledge and belief:

(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 the operation of the company.

March 29, 2012

By: /s/ Bobby W. Sandage, Jr.
Bobby W. Sandage, Jr., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Lucy Lu
Lucy Lu, M.D.
Chief Financial Officer
(Principal Financial Officer)